Management Operations of the National Cancer Institute That Influence the Governance of Science

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Management Operations of the National Cancer Institute

That Influence the Governance of Science

Office of the Director

National Cancer Institute
Bethesda, Maryland

Editors:

Vincent T. DeVita, Jr., M.D.
Louis M. Carrese

TABLE OF CONTENTS

Foreword

This issue of the Monograph series is concerned with the management operations of the National Cancer Institute (NCI). Over the years, these operations have received considerable attention from the Congress, the scientific community, and the lay public. In some instances, misinformation, insufficient information, and misunderstandings have resulted in erroneous opinions regarding performance in the overall management of the NCI and the coordination of the National Cancer Program.

This Monograph focuses on certain management operations that influence the governance of science at the NCI ranging from establishment of program priorities to the planning and budget processes, to the establishment of rigorous and standardized procedures for the review of research whether supported through grants, contracts, or conducted in our intramural laboratories. During the past 3 years, the Institute has implemented a series of initiatives which have improved and strengthened virtually every aspect of the management and administration of this large and complex national cancer research effort. Some of these improvements are discussed in the paper "The Governance of Science at the National Cancer Institute: A Perspective on Misperceptions," with a more detailed presentation in Appendix A, *Report on NCI Management Efforts and the Impact on Research.* This report was requested by the Senate Appropriations Committee in its report on the Fiscal Year 1983 budget for the Department of Health and Human Services (DHHS).

Appendix B, the *Guide to the Principal Investigator of NCI Contracts,* and Appendix C, the *NCI Manual for Contract Administration,* are official Institute documents that provide more detailed information in these two areas than is contained in the papers in the main body of the Monograph.

Although we have made the documents and papers describing these initiatives available to a wide spectrum of audiences, we believe that the periodic inclusion of papers on management issues in scientific publications will be a particularly important part of our efforts to keep the scientific community fully informed on the governance of science at the NCI. I am especially pleased that we could make our first venture in this effort in the Institute's Monograph series.

This volume is intended to serve as a useful reference document for some of the major NCI management operations about which questions are most frequently asked. As further improvements and efficiencies that influence the governance of science are achieved, they will be expeditiously communicated to provide current and accurate information continuously on the management of the National Cancer Program.

Vincent T. DeVita, Jr., M.D.
Director

Introduction

When science, like other endeavors, is conducted on a large scale with public funds, it is the responsibility of the sponsoring agency to provide a high degree of accountability both of the disposition of these funds and of the efficiency and effectiveness of the overall operation of the agency. In science, as in other areas, this accountability is achieved through a series of administrative activities and management functions, which, in their totality, are often referred to as "governance."

Governance is most successful when it is exercised with a measured understanding and appreciation of the nature of the activities and processes to be governed. For example, the consistent and rigorous application of the management procedures that assure maximum production efficiencies and profit in a successful industrial operation would probably stifle creativity and experience a lesser degree of success if similarly applied to the operations of science. Fortunately, the term "governance" provides one the opportunity to be selective because it has a broad spectrum of meaning ranging from the less forceful direction and supervision implied by the words "guide," "oversight," "administer," "husband," to the more forceful direction and supervision implicit in the words "control," "direct," "regulate," "restrain," and "sovereign authority" (The American Heritage Dictionary. Boston: Houghton Mifflin, 1976).

The National Cancer Institute (NCI) has paid particular attention to the governance of science by the careful selection and development of management procedures most suitable to the two major characteristics of the National Cancer Program: 1) the size of the Program in regard to commitment of national resources and the requirement for the careful management of these resources, and 2) the heterogenicity of the Program reflected in the wide variety of activities performed, ranging from investigator-initiated basic research requiring little governance to planned and targeted national programs requiring a greater degree of governance.

The papers included in this Monograph were prepared independently by the authors or NCI organizational units for other purposes and not specifically as a compendium for it. However, when presented together, they provide a good overview of the major management operations of the Institute and its attempt to arrive at the "best fit" for the governance of numerous research and related activities.

The first paper, "The Governance of Science at the National Cancer Institute: A Perspective on Misperceptions," discounts some of the insupportable misconceptions associated with the management of the Institute since the passage of the National Cancer Act and discusses the importance of some recent management changes to the governance of science at the NCI.

The second paper, "NCI Program Development and Coordination," describes the ways in which scientific programs are selected, priorities established, plans and budgets developed and reviewed, funds allocated, diverse activities coordinated between participating institutions, and how evaluations of both scientific programs and management activities are performed.

The next three papers are concerned with the more specific processes of program implementation and review. The use of grants, contracts, and cooperative agreements and the distinctions among these mechanisms of support are discussed in the paper on "The National Cancer Institute Contracting Process." The papers entitled "Peer Review of Contract Proposals at the National Cancer Institute" and "The National Cancer Institute Intramural Review Process" outline the rigorous scrutiny and standardized peer review applied to both extramural and intramural programs.

The overall governance of the NCI during the past 3 years presents the stabilization and fine tuning of those management procedures that have proved to be effective, the consolidation of certain administrative activities in the Office of the Director, and the introduction of new procedures for the improvement of specific management operations to meet current program needs, e.g., the establishment of a corporate decision-making process through the Institute's Executive Committee.

All changes have had one objective, i.e., the governance of science at the NCI that is at once rigorous enough to assure a high degree of public accountability and sensitive enough not to restrain or interfere with the essential exploratory and creative nature of the scientific process.

Louis M. Carrese
Vincent T. DeVita, Jr., M.D.

The Governance of Science at the National Cancer Institute: A Perspective on Misperceptions [1, 2]

Vincent T. DeVita, Jr. [3]

ABSTRACT—The National Cancer Program, because of its size, has always been and remains controversial. Some of these controversies have their roots in insupportable myths attending the passage of the Cancer Act in 1971 and the Institute's management of a rapidly changing program, rather than the science it supported. The National Cancer Institute has changed its management systems to improve the governance of science to allow for continual scrutiny, adjustment, or phase-out of programs that have served their purpose. This is necessary if we are to husband scarce research dollars in support of the plethora of opportunities presented by the powerful new knowledge derived from the current biological revolution. — Natl Cancer Inst Monogr 64: 1-5, 1984.

INTRODUCTION

The success of any complex, multifaceted scientific endeavor, such as the National Cancer Program (NCP), depends as much on the governance of science as on its conduct. This point is poorly appreciated by many investigators. How resources are allocated profoundly affects the stability of the scientific establishment. The decision to allocate resources to different areas of science, even in times of plentiful resources, must always be made by someone. This unavoidable truism is the very crux of the effective governance of science, but it sometimes appears to conflict with the treasured ideal of the spontaneity of investigator-initiated research. Because fiscal reserves are diminishing, improvements in management of the NCP affecting the allocation of resources have been our highest priority since 1980. These changes have allowed the Institute to support important new programs even in times of tight budget, an essential component of the successful governance of science. The ability to alter course in response to changing conditions and to plan ahead for the next decade will allow scientists supported by the National Cancer Institute (NCI) to continue to capitalize on the remarkable scientific advances of the 1970s.

MISPERCEPTIONS AND MYTHS

A recent communication to me from Dr. James D. Watson, Director of the Cold Spring Harbor Laboratory, in regard to an often controversial NCI scientific program, helps to illustrate the importance to all of us of the proper governance of science. He wrote, "Given the still prevalent unfair public misconception that the NCI Tumor Virus Program was a failure, and the new strong possibility (fact?) that most if not all of viral oncogenes have their human counterparts, the time is more than ripe for NCI to point out how well the public purse has, in fact, been used." I would concur with Dr. Watson's views. Recent discoveries of retrovirus oncogenes and their human homologs make it reasonable for one to state that few areas of research have been so fruitful. We are closer to understanding the underlying abnormality of growth that is cancer than the architects of the NCP could have imagined in 1971. In addition, the first credible human RNA tumor virus responsible for a T-cell leukemia-lymphoma was identified recently, fulfilling a primary goal of the special Virus Leukemia Program at its inception in 1964. Yet Dr. Watson mentions the "prevalent unfair public misconception . . ." How did that perception about the program that has been so successful come to be? Can it be generalized to the whole NCP? I believe it can; it has its roots in the governance of science.

The controversy that has swirled around the Cancer Program centers around four major myths that remain difficult to dispel.

First, the Cancer Program was controversial because expectations for the immediate, practical application of the fruits of basic research were, in some cases, too high. Judging from the first public criticism, some critics naively expected control of cancer by 1976, a mere 4 years after funding to NCI was increased! The heightening of expectations of this kind was not generally fueled by knowledgeable laypersons, basic scientists, clinical investigators, or physicians who understood the long, drawn-out struggle necessary to unravel the complicated biology of cancer. Even so, the signs of success, now evident everywhere, indicate that many of the realistic scientific expectations have been met and exceeded.

The second controversy relates to the standard belief that money cannot buy good ideas, and hence the resistance on the part of a large segment of the scientific community to sharply increased resources to the NCP in the early 1970s. This is the greatest myth of all. Money does, in fact, buy more good ideas because, if more gifted scientists are put to

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[1] Adapted from a dedicatory address for the Reginald Harris Building at Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, May 27, 1982.

[2] This paper was previously published in *Cancer Research* 43:3969–3973, 1983, and is reprinted here with the permission of the publisher.

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work, they originate good ideas and create momentum. The confusion is created by the lag between the availability of increased resources and the establishment of excellent productive research facilities that foster new ideas. The time lag makes conceptualization of the relationship between the availability of increased resources and the flow of new ideas and discoveries difficult. This is especially true for the public who must also balance the additional time lag from a new discovery to its practical application in this complex time equation. In truth, this is part of the NCP's problem; the time lapse between the initial flow of resources and enhanced productivity occurred between 1972 and 1976 for the NCP. Since 1970, the number of new grantees funded by NCI has increased 4.5-fold and the annual cost of its main research grant, the R01, has doubled. However, in constant dollars, the NCI budget has increased only 2.5-fold. Now the number of good research programs, a mark of success of the NCP, has outstripped our ability to support them fully.

The third controversy centered around the canard that the Cancer Program grew at the expense of the other Institutes of the National Institutes of Health (NIH). A quick review of the budgets of all NIH Institutes between 1971 and 1976, the period of rapid growth for the Cancer Program, shows that this is simply not so. Although the NCI's budget increased from approximately 200 million dollars to over three-quarters of a billion, NIH's budget increased from 1.2 to 2.3 billion dollars. In some cases, budgets of other Institutes increased at rates faster than they had before the passage of the National Cancer Act. Finally, it is not reasonable for one to assume that the increased cancer appropriations would otherwise have been divided among the other Institutes to add to their already increasing budgets.

The fourth controversy emanated from NCI's use of contracts to fund research. This point is pivotal in the debate over the governance of science. During 1971–76, the period of rapid growth, the NCI used the contract mechanism to initiate certain kinds of programs because it was the most efficacious or time-saving process. In fact, between 1972 and 1975, the NCI disbursed more money through contracts than through the R01 and P01 grants, its main instruments for funding investigator-initiated research. Contracts were foreign to most basic researchers and the NIH community. In contrast to grants, regardless of the source of the idea, a request for contract proposal (RFP) must be issued by the Institute's staff, whereas grant applications originate with the investigator. Contracts also implied (often incorrectly) NCI's direction of research (which no one, then or now, likes) and, finally, contracts were awarded outside the traditional peer review system. Thus the use of contracts brought intense scrutiny to and criticism of all of NCI that almost eclipsed the significant progress being made. The Virus Cancer Program, originally a targeted research program searching for human cancer viruses, was supported mainly by contracts and was the recipient of a large portion of the increased resources after 1971. Because the Virus Cancer Program had started before most other NCI programs, and because NCI's top-level management and intramural staff in the Division of Cancer Cause and Prevention were weighted heavily toward viral oncology, the notion prevailed that in the Institute's etiology research efforts biases existed in the allocations of resources in favor of the viral oncology program, especially its intramural component, at the expense of other approaches to cancer prevention. Again, the use of the contract instrument was the central issue in all this criticism. It was viewed suspiciously, as a potential means for diverting monies to favored persons and programs, intramural and extramural, and away from the competitive pool and the normal marketplace of ideas.

Although NCI's budget grew rapidly between 1972 and 1976, the rate of budget growth slowed between 1976 and 1980 to a rate not even sufficient to keep pace with inflation. As resources became less plentiful, competing interests within the cancer research community began to challenge how priorities were set and how systems for allocating scarce resources were functioning. Around 1976, for example, controversies over allocation of resources between prevention and treatment arose. Within the prevention program itself, arguments over allocation of resources between support for research on chemical and viral carcinogenesis were particularly acrimonious in the scientific community. In both cases, the issues also were debated in the public press. Some critical scientists framed their desire for greater funding for their particular area of research as lack of success of a competing area during the time lag required for these areas to grow. The press found such internal discord unparalleled grist for the mill, and the misperceptions about progress in the NCP spilled out into the public arena.

The situations just described as they were debated in the scientific and public press are, in my view, the chief source of public misperceptions about the success of the NCP in general and the success of the Virus Cancer Program in particular. However, it should be noted that none of the points relate to the actual merit of science, although they do serve to illustrate how lack of attention to the governance of science can affect science itself.

MANAGEMENT PRACTICES AND THE GOVERNANCE OF SCIENCE

In 1980, we recognized two factors that contributed to the controversies: 1) During the early years after passage of the National Cancer Act, the management system of the Institute had not kept pace with the allocation of resources and responsibilities to be managed. This was particularly true of details of contract financial management because the main goal of the early architects of the Program had been to establish new programs with all possible speed. 2) A closed loop system had been used for allocation of resources. Once funds had been committed to a program area, that commitment was maintained. A system for redistribution of resources across program lines in response to the changing scientific opportunities had never evolved. New programs needed resources to get started and, between 1980 and 1982, new resources were scarce; NCI's budget actually decreased by 1.5%. Although the old system functioned reasonably well when monies increased at a

rapid rate (as most systems do), it had become untenable in a time of shrinking budgets.

MANAGEMENT CHANGES AT THE NATIONAL CANCER INSTITUTE SINCE 1980

Between 1980 and 1982, the Institute put into effect major changes to correct these problems. The main elements of these changes are: 1) The processes of decision-making and setting of priorities for each NCI division were elevated to public view and conducted with expert advice from four divisional Boards of Scientific Counselors (BSC), constituted entirely of highly qualified non-Government scientists, representing competing priorities within each research thrust. These Boards replaced the multitude of special interest advisory committees that had previously acted autonomously and advised in isolation, and their function is closely linked to the National Cancer Advisory Board (NCAB). 2) Decisions based on the advice received from all these advisory bodies are acted on corporately by a newly staffed NCI Executive Committee, comprised of a compact group of scientist-administrators with broad research expertise, each of whom is responsible for a major program segment at NCI. All programs are now scrutinized periodically in open forum to justify their existence. 3) The NCI's business management systems, previously connected loosely and scattered throughout the operating divisions, were overhauled and centralized in the Office of the Director under the Associate Director for Administrative Management. Management policy can now be implemented in a unified fashion. 4) The peer review and financial management of contracts were streamlined. The dual review of contract-supported projects is the obverse of grants. By regulation, the concept of the project is reviewed first by a group separate from those who review the merit of proposals submitted to accomplish its goals. The concept of a project support by a contract is now reviewed by the divisional BSC before issuance of a Request for Proposal (RFP). Peer review of the merit of responses to the RFP for *all* contracts (research, resource, and those used to support the intramural program) was transferred from divisions responsible for the specific scientific program into NCI's review division, the Division of Extramural Activities, and performed by chartered committees of extramural scientists. Peer review of contracts now approximates that of grants. 5) Because NCI's intramural program is highly visible and because we are convinced that the quality of research supported by this program is equal to research supported in NCI's R01 and P01 extramural programs, we believed there could be no semblance of double standard in its peer review. A new peer review process was established on an Institute-wide basis. Each intramural laboratory is "site-visited" periodically by subcommittees of its divisional BSC supplemented by additional scientific peers. Before and during these site visits, branch and laboratory chiefs are required to describe their past research and future plans as well as all of the budgets, including any support through contracts, so their research can be judged on the basis of its cost-effectiveness. Renewal of any resource contracts to an intramural laboratory is timed to coincide with each site visit and, before award, requires concept approval of the BSC with recommendation of the site visit team. One year following each site visit, a follow-up report is made to the divisional Board to report on implementation of the recommendations made. As a result of the recommendations made in the site visit reports, major staff changes and consolidation of our intramural program have occurred over 3 years that have enabled us to redistribute resources and therefore limit its growth to a rate comparable to that of the extramural program while preserving its unique flavor and position in the scientific community. Often criticized off-site laboratories have been closed and relocated to the Bethesda campus or the Frederick Cancer Research Facility (FCRF) to make better use of government-owned laboratory facilities. This process has been completed for the entire NCI intramural program.

The new intramural peer review system has worked so well that, when our intramural program was meticulously investigated by the Government Accounting Office at the behest of Senator Hawkins, with specific instructions to compare the quality of the peer review system for the intramural program to that for grantees, the system now in use was recognized as comparable to that for the extramural program in the ability of the program staff to judge the quality of the research and foster change. This review process and details of changes in NCI's management systems are described in two chapters included in this monograph (p 45 and p 75).

All these changes have contributed to improvements in NCI's governance of science and have enabled the Institute to survive the most intense Congressional scrutiny ever given a similar organization. As a result, NCI might now be characterized as "squeaky clean." The new corporate management system, functioning with detailed advice from the four deeply involved multidisciplinary BSC, the NCAB, and the President's Cancer Panel, all in open forum, enabled the NCI Executive Committee to reprogram over $80 million in resources (the majority from contracts), to help absorb a loss of approximately $200 million in purchasing power between 1980 and 1982, and to maintain support for its highest priority basic research in the face of a declining budget. With greater confidence in its review and management, NCI has salvaged the contract as a vehicle of support for research when its use is judged appropriate. In a sense, the contract mechanism itself had been maligned. Contrary to popular belief, a contract could be used to support research programs. Appropriate use of contracts depended on where and how they were initiated and reviewed and whether a mechanism existed to assure that contract programs could be phased out when the activities they supported were no longer of the highest priority, or whether they could be converted to grants or cooperative agreement mechanisms when these were judged more suitable.

Five other steps were taken to lend stability to the support of research:

1) The NCI staff, with advice and support from the President's Cancer Panel, and NCAB, proposed and arranged for the transfer of its chemical bioassay program, with all its resources ($45.6 million and 80 positions), to the

National Institute of Environmental Health Sciences (NIEHS). This controversial step was taken for two reasons, the first of which was that, if the program were started today, it would need to address the multiple potential adverse effects of chemicals, such as those on the reproductive system, fetal development, and behavior, as well as the carcinogenic potential of chemicals, which is a broader testing mission more appropriately within the scope of NIEHS. Secondly, it freed NCI staff from the task of managing and financing a routine testing program and allowed them to devote their full energies and resources to the support of basic research and the application of the results of basic research in cancer prevention. The NCI wished to emphasize the interrelationship of its basic research programs, such as biological and chemical carcinogenesis and epidemiology, aimed at giving a better understanding of the mechanisms of carcinogenesis.

2) As a result of this shift in emphasis, a major new initiative was begun in cancer prevention. In our newest Division, the Division of Resources, Centers and Community Activities (DRCCA), which administers that portion of the budget devoted to the Cancer Control Program, we have shifted resources to emphasize those applications of the results of basic research designed to interfere with the late stages of the carcinogenic process, presumably related to cancer promotion. Prospective clinical studies of materials known to interrupt or impede cancer causation in rodents are now being launched; these substances often appear as positive variables in the numerous epidemiologic studies supported by the increased resources made available to the Program in the early 1970s.

3) Also in the early 1970s, the Institute established the Organ Site Program as a means for assuring emphasis on research in neglected common tumors. Because, in the past decade, the attitudes of basic researchers changed rapidly toward research related to various common cancers and the need to complete the separation of program direction and its review (accomplished for all other grant and contract programs), the NCAB recommended that NCI convert the Organ Site Program to a new format referred to as the "Organ Systems Program." The new format returns the review of organ site grants to the regular NIH review systems or, when appropriate, to those of NCI. This move should broaden the Program's scientific base by allowing a new extramural organ system coordinating center to scan the entire scientific horizon for research advances ready for clinical application in the common tumors. The controversy generated by this organizational change, which has been debated at Board meetings and in the Congress, exemplifies the difficulty in allocation of scarce resources. The proposal made by a subcommittee of the NCAB and accepted unanimously by the full Board and NCI staff after a thorough scientific review preserves the emphasis but increases the Program's flexibility to respond to new advances in basic research that require rapid application.

4) A major change was made in the management of the Frederick facility. Established in 1971 with the passage of the Cancer Act to "convert swords into plowshares," it is a government-owned, contractor-operated facility. Because it is operated by a contractor, this contract must be recompeted periodically. In May 1980, 2 years before it was scheduled for recompetition, the NCI asked the NCAB to consider, in addition to other issues inherent in contract recompetition, whether the work at Frederick should be continued. After site visits and detailed analyses of the results of review of the scientific programs at FCRF, it was agreed that the Program was of high quality scientifically and merited continued support. The NCI Executive Committee proposed and the NCAB agreed to proceed under the following guidelines: *a*) The research portion of the contract was to be decreased by 20% because of the lean budgets anticipated for all of NCI (ultimately, it was decreased by 29%). *b*) Concurrent with the review of NCI's intramural program and the decision to move off-site laboratories from rented space in the Bethesda area, NCI was urged to utilize the excellent laboratory facilities of FCRF to achieve a better balance between contractor and intramural scientists using space made available by the reduction in the research portion of the contract. *c*) Because criticism was expressed during the previous investigation by the Government Accounting Office of the noncompetitive nature of a government-owned, contractor-operated contract this large, the NCAB agreed that the Institute should take whatever steps were necessary to increase the competitive nature of the contract. *d*) Because the fragmented nature of the relationship between NCI and its FCRF contractor-supported science and its review and management caused concern, a consolidation of management and review under a single NCI Associate Director and scientific advisory committee was effected.

The recompetition of the FCRF contract, a massive undertaking unique in the history of such facilities, involved over 1,000 NCI and contractor staff and took 2½ years for completion. The contract was made more competitive by division into 5 components. Proposals for each of the 5 components were subjected to rigorous peer review by panels of non-Federal expert consultants. The result of this enormous effort is that all initial goals have been met. Now a single FCRF advisory committee composed of distinguished extramural scientists oversees the consolidated contractor-supported research program and its review. Several of the committee members are chosen from the divisional BSC because of their expertise in the comparative evaluation of contractor science relative to intramural science. The NCI program director is an NCI Associate Director (and a member of NCI's Executive Committee) who works through an on-site manager to interact with the principal investigator of the research portion of the contract. Finally and most importantly, the overall combined cost of the NCI intramural program components moved to FCRF, and the FCRF contracts are 2% lower in 1983 than were the same components as they existed in 1980.

5) Lastly, the NCI Executive Committee, with the approval of the NCAB, established a series of funding plans aimed at stretching research dollars allocated to the grant pool swelled to a modest degree by the reprogramming efforts described above. Details of NCI's budget development and the rationale for these funding plans will be the subject of a subsequent publication.

CONSEQUENCES FOR THE NCI TUMOR VIRUS PROGRAM

Despite some initial anxiety, the Viral Oncology Program has fared well in this shift and reallocation of resources; in 1970, its total program resources were $21 million. These peaked in 1979 at $110 million, and in 1983 its budget was $90 million. This decrease of $20 million is mainly the result of a decrease of $30 million in contracts, much of which came from intramural support contracts, concomitant with an increase of $10 million in grants. This shift from contracts to grants allowed NCI to maintain the health and balance in this program because the grants in the Viral Oncology Program are generally less costly than contracts. It also enhanced the diversity in research more easily achieved by investigator-initiated projects and maintained the impressive momentum of this important scientific area. That the early success of the NCI's contract-supported Virus Cancer Program made it possible subsequently to use the grant as a vehicle of support should not be overlooked. The recent identification of both retroviral oncogenes in human tissue and the first credible human retrovirus was greatly facilitated by the initial use of the contract, an instrument usually regarded as more appropriate for the support of applied research.

CONCLUSION

Those who manage the NCP face two major challenges in the 1980s. The first is to support the momentum of the biological revolution in a time of scarce resources, which will require the kind of management system now in place and the continued willingness of everyone to share resources across program boundaries and to change or phase-out, or both, some programs to allow support for new research areas, even if resources dwindle. The second challenge is often overlooked in the management of scientific resources. In the NCP, the essence of the concept of the Program must be kept intact as conceived originally; not only is basic research to be supported but also the results of this research are to be applied when appropriate. This is particularly important because, in addition to opportunities for the application of results of research in diagnosis and treatment, opportunities are now plentiful for applying results of basic research in prevention.

In a sense, the Cancer Program can be regarded as an unusual and fragile biologic organism with a head at each end. One end is concerned with basic research and the other with the application of the results of basic research. The organism is unable to survive if either head is severed. The reason the second challenge assumes importance is that food for both ends of the organism flows, surprisingly enough, at a rate proportional to the Program's willingness to apply the results of basic research. That is how the Cancer Program began in the first place. The delicate balance of sufficient support for basic research and the application of its results are the essence of the governance of science and must be promulgated in public view by individuals with a broad overview of the program. Although support of basic research is and always will be our first priority, the public, the Congress, and many scientists as well get cranky when the Program staff show an unwillingness to apply research results. At this point, the organism seems to turn upon itself, the public hears only negative arguments, and resources for the support of the entire Program diminish, with proportionally less effort devoted to basic research.

We have often been asked if the NCP has been a success. While I acknowledge a bias, my answer is an unqualified "yes." The success of the Virus Cancer Program which prompted this essay is a good example. Since its inception, this Program has cost almost $1 billion. If asked what I would pay now for the information generated by that Program, I would say that the extraordinarily powerful new knowledge available to us as a result of this investment would make the entire budget allocated to the NCP since the passage of the Cancer Act worthwhile. There may well be practical applications of this work in the prevention, diagnosis, and treatment of cancer that constitute a significant paradigm change. The work in viral oncology has indeed yielded a trust fund of information, the dividend of which defies the imagination.

The misperception of the success of the Virus Cancer Program to which Dr. Watson referred relates to the approach to the allocation of resources in the early 1970s. The management problem in the Virus Cancer Program was in its switching mechanism, i.e., the decision-making process about when and under what circumstances we would switch from contracts to grants (and back) and when the work switched from the more applied to the basic (and back). Under the old system, these points were not reexamined periodically in the public arena and contracts were continued for too long. With NCI's present system, this point is reexamined for each contract-supported program by that program's divisional BSC and the NCI Executive Committee on a continuing basis.

The public purse mentioned by Dr. Watson has been well used, but the reasons for the public misperception should also be clear. We have learned a valuable lesson: To have the public trust and support to continue the kinds of research we want and need, we cannot neglect the governance of science.

National Cancer Institute Program Development and Coordination

Louis M. Carrese [1]

ABSTRACT—The development and coordination of programs for a large and complex effort like the National Cancer Program (NCP) entails the performance of diverse management, administrative, and scientific activities. These activities range from the review and selection of programs and projects for implementation, planning and budget processes which provide a base for resource allocation, setting of program priorities when necessary, evaluation of program outcomes, and the establishment of mechanisms for the coordination and collaboration of the activities performed by the Federal and private sector participants in the NCP. — Natl Cancer Inst Monogr 64: 7–20, 1984.

Program development requires decisions concerning the initiation, maintenance, reduction, and termination of programs. From these decisions, priorities are established, programs are selected for planning, resources are allocated for implementation, programs are coordinated, and criteria and approaches are developed for evaluation of these programs during and at the end of their period of performance.

These activities are performed by National Cancer Institute (NCI) management and program staff and a series of chartered advisory committees (*see* fig. 2.1). The conceptual and operational aspects of program development are depicted in figure 2.2. Beginning with the generation of new ideas from a variety of sources, we have shown the major phases of budget development and the contract management process keyed to the NCI organizational unit or advisory committee performing the functions. Operating program and budget decisions are the results of the interaction between corporate management represented by the Director and the Executive Committee and the advisory function represented by the National Cancer Advisory Board (NCAB) and the Boards of Scientific Counselors (BSC) of the four divisions with program responsibilities. The entire review function (grants and contracts) is knitted together by the Division of Extramural Activities (DEA). The President's Cancer Panel provides a general oversight for the National Cancer Program (NCP) with particular attention to any administrative roadblocks which may be impeding the progress of the program. Each of the activities involved in program development is discussed separately.

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SETTING OF PRIORITIES AND PROGRAM SELECTION

Realistic limitations on the availability of people, facilities, and funds usually preclude the implementation of all feasible and desirable programs at the same time. Therefore, a system is needed for selection of the most worthwhile programs and activities for implementation on the basis of such factors as need, urgency, importance, merit, and high probability of success.

The Director, NCI, who bears the responsibility for setting priorities for implementing new programs or for changing (expanding, reducing, terminating) ongoing programs, bases these decisions on extensive consultation with groups of scientists and administrators, both internal and external. Within the NCP, advice on priority setting and program selection is sought from at least seven major sources.

The Congress

The Director's annual presentation of plans, budget, and program priorities to the appropriate Congressional committees reflects the extensive review of both internal and external scientific advisory committees. The Congress may at times conduct a review of areas it considers to be of high priority through oversight hearings, special studies by the General Accounting Office (GAO) or the Office of Technology Assessment (OTA), etc. These reviews may result in specific legislative mandates or directives for implementation of specific programs in these areas. Such Congressional interest resulted in the establishment of the Cancer Chemotherapy National Service Center in 1955 (later the Cancer Chemotherapy Program), which began the large-scale acquisition and testing of compounds for anticancer properties; the initiation of the Special Virus Leukemia Program in 1964 (later the Virus Cancer Program), which initially involved a national effort to isolate a human leukemia virus; the establishment of the Cancer Control Program in 1971 to develop and demonstrate approaches for translating research results to the practice of medicine; the establishment in 1971 of the International Cancer Research Data Bank to ensure more effective communication and sharing of cancer research information on a worldwide basis; and in 1977 the designation of nutrition research as an area for emphasis and expansion.

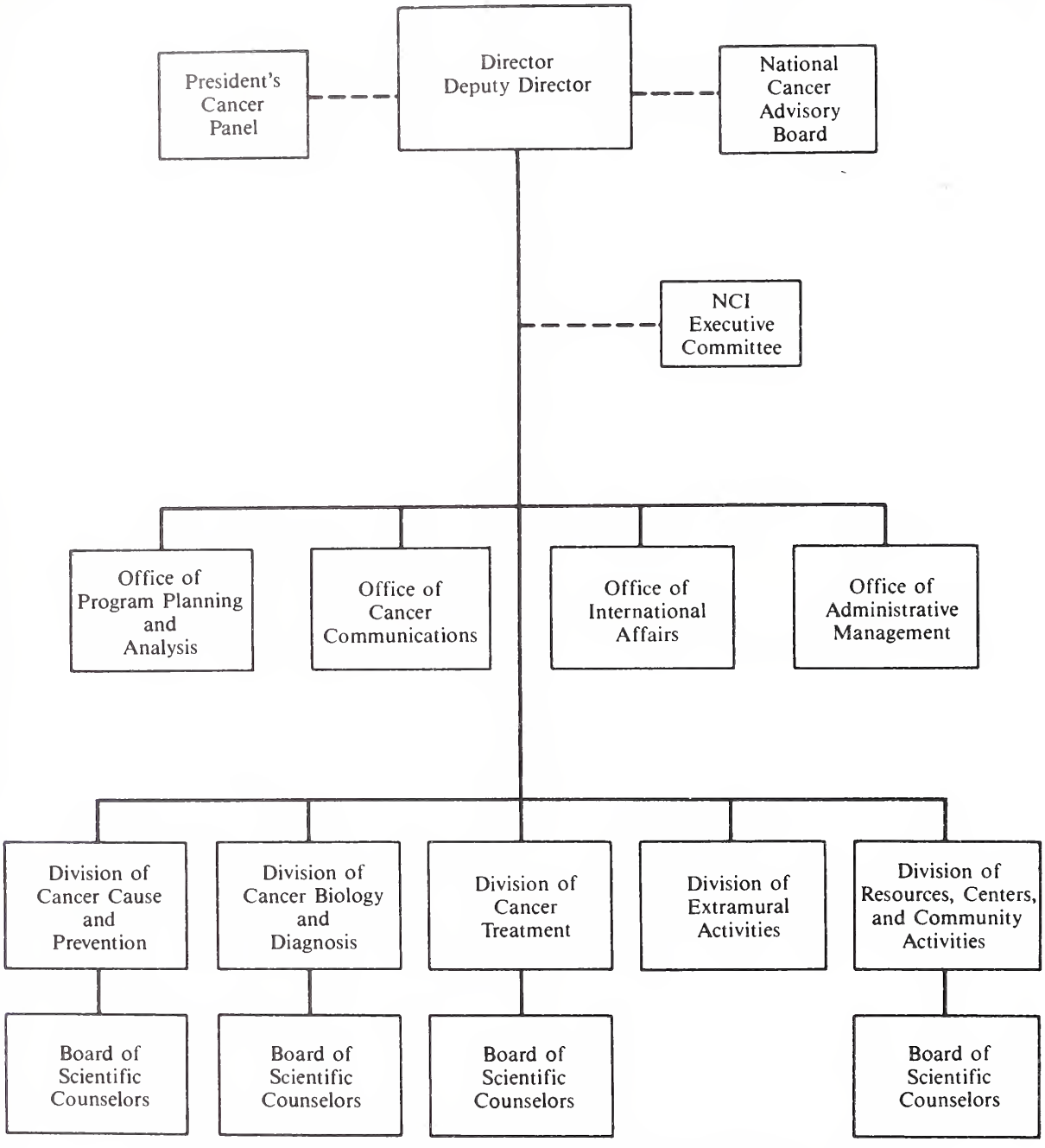

FIGURE 2.1.—Management and program staff and chartered advisory committees of the NCI.

Department of Health and Human Services and the Public Health Service

The Department of Health and Human Services (DHHS) reviews the proposed programs and budgets of its principal operating components, including the justification of program priorities. Program changes may be made on the basis of this review, and the Department may identify certain programs as particularly important and deserving of special emphasis. Often these programs represent efforts by the various DHHS health agencies to address research in broad program areas on a cross-agency coooperative basis. After a lead agency has been selected, other agencies participate to the extent to which the proposed work reflects their

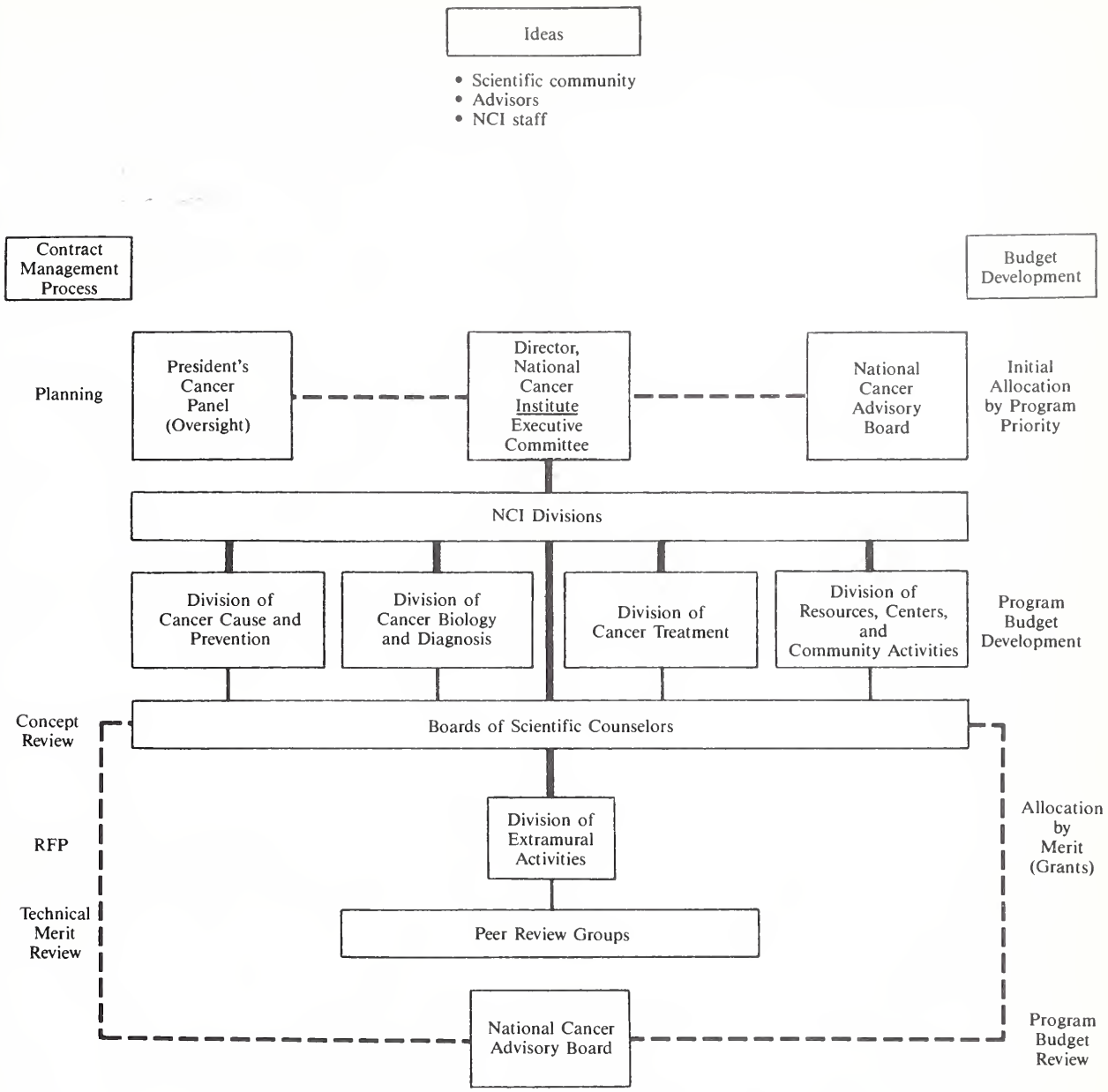

FIGURE 2.2.—Conceptual and operational aspects of program development.

missions; their participation includes shared planning, information, and funding. A good example of this cross-agency cooperation in a priority area is the effort in low-level ionizing radiation.

In 1978, legislation was enacted which directed the Secretary, DHHS, to 1) establish a comprehensive program of research into the biological effects of low-level ionizing radiation, and 2) conduct a comprehensive review of Federal programs of research into the biological effects of ionizing radiation. Soon after, the Interagency Radiation Research Committee was established by the Secretary to include representatives from all Federal agencies which conduct or sponsor research involving any aspect of radiation biology or the assessment of human health risks resulting from exposure to ionizing radiation. This Committee, which is currently chaired by the Director of the National Institutes of Health (NIH), is responsible for coordinating the planning, implementation, and evaluation of a comprehensive Federal radiation research program on the biological effects of ionizing radiation and for ensuring

that this program is performed efficiently and with the highest scientific standards.

National Institutes of Health

The proposed programs, priorities, and budgets of the research institutes and supporting divisions are reviewed by the Director, NIH, before their submission to DHHS. These reviews take place annually and are concerned primarily with justification of program priorities, program selections, and resource allocation. Proposed institute priorities may be reordered as a result of discussion at these meetings.

Since 1980, the NIH has sought to stabilize the biomedical science base by assigning the highest priority to funding a minimum of 5,000 new competing investigator-initiated grants. This unusual approach was considered essential to the maintenance of a viable biomedical research enterprise. This action directly affects the program priority setting of the Institutes and Divisions of the NIH and has proved to be an effective procedure for implementing the research priorities established by the scientific community through its participation in the peer review process, which is discussed below.

The President's Cancer Panel

The President's Cancer Panel, established by the National Cancer Act of 1971, consists of 3 individuals appointed by the President of the United States. The Panel is mandated to meet at least four times each year to report to the President any matters that impede the efficiency and effectiveness of the National Cancer Program.

Traditionally, the Panel has held most of its meetings in the Washington area, usually to coincide with the meetings of the NCAB to enhance communication and information exchange between the 2 groups and to facilitate coordination of special activities as necessary. Also, one of the fixed NCAB agenda items is the report of the chairman of the President's Cancer Panel. In 1982, the Panel initiated a new activity, that of taking public testimony on issues of importance to the NCP at open meetings held in different parts of the country. Meetings were held in Boston, Los Angeles, Chicago, Seattle, and Houston where the Panel examined alternatives and options proposed by scientists regarding possible modifications of the peer review and grant award mechanisms at the NCI and the NIH.

During 1983, as a result of the consultations with members of the scientific community at its meetings around the country, the Panel initiated a study of the grant mechanisms available to established research investigators. An ad hoc working group was established and charged with the responsibility to draft recommendations and guidelines for an Outstanding Investigator Grant. The Outstanding Investigator Grant is intended to provide stable financial support and research flexibility over a long but defined period.

The Panel plans to continue to hold meetings on issues and concerns of importance to the nation's scientists and to respond to these concerns by appropriate recommendations to the President; Director, NCI; and the Director, NIH.

National Cancer Advisory Board

The NCAB influences program priorities in three major ways:

1) It is the legally constituted body that performs the second phase of the review of research grant applications (the first phase is performed by the Initial Review Groups discussed below) and recommends approval or disapproval to the Director, NCI. The NCAB may coneur with the priorities recommended by the Initial Review Groups or disagree with a recommended action on a single grant and can change the proposed action.

2) The annual November NCAB Program Review Meeting is devoted to a summary of all scientific activities and business transactions by the operating Divisions. This is done by the Division Directors and their BSC Chairmen from the standpoint of scientific program priorities and budgetary requirements established from deliberations of the respective divisional boards with Institute management staff. Another important aspect of the annual review meeting involves the selected presentations by scientists working in extramural or intramural laboratories, or both, and clinical investigators of the achievements of certain scientific programs having a potentially highly significant impact upon solving the cancer problem. Also included is a discussion of particularly promising opportunities and leads which should be pursued.

3) Through its several subcommittees, the NCAB can also provide the Director with its recommendations on specific programs and program priorities throughout the year. Since 1980, the Director has asked the NCAB to participate directly in the establishment of program priorities under various budget situations. This participation has been accomplished by detailed program and budget discussions by the Subcommittee on Planning and Budget and by mail ballot followed by discussion at subcommittee and full Board meetings.

Division Directors and Boards of Scientific Counselors

Each of the four Divisions with direct program responsibility has a BSC which meets at least three times a year to review divisional intramural and extramural programs and budgets and to provide to each Division Director advice and recommendations on program content and priorities. Each BSC consists of between 15 to 20 members selected for high scientific qualifications in areas reflective of the Division's total research program. Although regulations require that the Chairman and at least 75% of the members be non-Federal employees, in practice this is rarely true. Currently, all members of the 4 BSC are non-Federal employees. In addition to providing advice on program priorities and budget, the BSC also perform the concept review of each proposed new contract and contract recompetition, provide advice to the Division Director on unusual management issues, and perform the peer review of intramural research.

The interaction between each BSC and divisional staff is characteristically dynamic, candid, and productive. Thus the actions of the BSC constitute a major assistance to each Division Director in making decisions concerning priorities, content, size, and direction of the Division's

programs and in making recommendations to the Director, NCI, on the overall effort of the Institute. (For a more complete and detailed description of the BSC function, *see* the chapter on the Intramural Review Program.)

Initial Review Groups or Study Sections

The review of research proposals by peers of the applicants has been a cardinal factor in the development and maintenance of high standards of excellence in NIH programs.

The "dual" peer review system used by the NCI and other Institutes of the NIH is based on two sequential levels of review mandated by statute. The first or initial level of the dual review is performed by Initial Review Groups, also known as Study Sections [managed by the Division of Research Grants, and as Review Committees managed by the DEA, NCI]. The second level review is performed by chartered national advisory boards or councils (*see* previous description of NCAB functions).

The Study Sections usually consist of 12 to 20 members who are primarily non-Federal scientists appointed by the Director, NIH. These review groups are established and chartered by the Secretary, DHHS. They primarily review and evaluate the scientific merit of investigator-initiated, individual project grant applications (R01, R23, K04) and fellowship applications (F32, F33). However, a number of special grant mechanisms have been developed that meet the particular programmatic needs of separate NIH Bureaus, Institutes, and Divisions (BID).

In the NCI, the DEA uses Review Committees for the initial peer review of highly specialized grant applications, such as Program Project Grants (P01), Cancer Control Grants (R18), Cancer Center Support Grants (P30), Clinical Education Grants (R25), Training Grants (T32), Construction Grants (C06), and Cooperative Group Clinical Trials Agreements (U10). Other grant instruments are reviewed as special needs arise.

The Review Committees managed by the DEA also differ from Study Sections with respect to authority for establishment and appointment of members. As mandated by the National Cancer Act of 1971, the Director, NCI, was given direct authority to establish and charter Review Committees and appoint members. This authority is unique to the NCI compared with other NIH BID.

The end result of this highly detailed, extensive analysis and evaluation is the assignment to each application of a numerical priority for funding. Through this process of peer review, the scientific community expresses its collective opinion about the highest priorities for research by identifying areas of science that show the greatest promise of solving disease problems.

The NCI has steadily increased the percentage of its budget allocated to investigator-initiated research from 49.3% in fiscal year (FY) 1973 to 79.2% estimated for FY 1984. This increase, coupled with the NIH policy of stabilizing the science base for investigator-initiated research, effectively demonstrates that the setting of priorities and program selection for a major portion of the total NCI effort are the end products of the peer review system.

PLANNING

Planning encompasses activities ranging from the development of a strategic plan for a national program to the establishment of an annual budget for a single project. To be effective, planning must be closely related to budgetary operations and to evaluation activities, with a continual feedback of information from these activities.

Planning is the "organized thinking" of an individual or a group of individuals. Its purpose is the attainment of a consensus about which directions (broad objectives) appear most promising and which alternative methods (courses of action) and means (organization and resources) are needed to implement the desired courses of action so as to solve a problem or to achieve the objectives of a program. The initial plan is rarely valid for the life of a major program but must be updated as often as changing requirements dictate. Plans provide management a reference for making rational decisions regarding the pursuit of findings, leads, and opportunities; a basis for assessing accountability for the use of public funds; and an effective mechanism for the efficient organization and use of available knowledge and resources.

At the NCI, planning is accomplished at three major levels of operation: the national or strategic, the individual program, and the individual project. The first two levels are group activities, whereas project planning (development of the experimental design) is strictly the domain of the individual scientist. Planning at the strategic and individual program levels is primarily concerned with planning *for* science rather than the planning *of* science that takes place at the project level by whatever means or approaches the individual investigator considers appropriate. Strategic and program level planning activities are conducted with the participation of both Federal and non-Federal scientists. Program plans are usually updated on a "rolling" basis by the program staff as required by changing conditions and new information.

Program plans are used in a variety of ways by program staffs. At one end of the spectrum, once the planning sessions have been completed and the intellectual exploration of a particular problem has reached an end point, the actual plan may serve only as a general and occasional reference. At the other extreme, the planning group may develop a detailed operational plan, which becomes the basis for making budget allocations, tracking the program, and changing program directions.

Although the Office of Program Planning and Analysis is organizationally located in the Office of the Director (OD), NCI, major planning activities are not a central function of the OD but rather are a cooperative effort between the OD planning staff and the operating Divisions. The Office of Program Planning and Analysis coordinates the development of major planning documents and reports and of planning activities that cut across other NIH Institutes or Federal agencies, or both. It performs a service function by providing experienced professional staff who, with divisional staff, form teams to accomplish specific planning requirements. The extent to which formal planning techniques are used is at the discretion of the planning team.

The integration of the planning and budgeting processes is critical if program operations are to reflect the content of a plan; otherwise, the planning function becomes just an exercise. Planning and budget staff members of NCI coordinate their activities throughout each planning and budget cycle rather than only at the beginning and the end. Therefore, by the time the substantive content of a plan for a given program has been completed, estimates of cost and other resource requirements have also been developed.

BUDGET PROCESS[2]

The NCI is unique among Federal agencies in that the National Cancer Act of 1971 established the mandate that NCI "prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate." This special budget which does not pass through regular Department budget reviews has come to be known as the By-Pass Budget. In addition, the Institute prepares a budget as do other components of the NIH. The budget formulation process for NCI, therefore, entails the simultaneous preparation of two distinct budgets: 1) the By-Pass Budget which represents the professional judgment of advisory bodies, i.e., the President's Cancer Panel, the NCAB, and the BSC of each Division; and 2) the budget developed within the Administration's guidelines. The budgetary process included below will describe elements of both.

The Institute is continually involved in budgets covering 3 fiscal years; during development of the By-Pass Budget, 4 budgets are in some stage of implementation. For example, in May 1983, the Institute was obligating funds appropriated for FY 1983; presenting the President's Budget and testifying before the Congress on the budget that will be effective for the next fiscal year (FY 1984), which started on October 1, 1983; preparing the NCI portion of the Department's preliminary budget for FY 1985, which starts on October 1, 1984; and preparing the By-Pass Budget for FY 1985 in conformance with policy guidance from the NCAB and other advisory bodies.

BUDGET CYCLE

Budget Formation

By-Pass Budget

The Institute normally will develop the initial budget assumptions for the By-Pass Budget in March about 18 months before the start of the fiscal year. These parameters are then presented to members of the NCAB Subcommittee on Planning and Budget in the early spring at a meeting with the NCI Executive Committee. Discussions at this meeting center on areas of emphasis, scientific opportunity, budget levels, and policies. With this advice, the NCI then prepares a draft of the NCI Preliminary Budget for presentation to the full NCAB at its spring meeting (normally in May). During the May meeting, after a thorough review and discussion, additional modifications may be made to this Preliminary Budget.

In the ensuing months, the Institute develops extensive narrative and tabular justification material for this budget. By September 15, the By-Pass Budget is sent to the President for his consideration.

Administration Budget

Concurrent with the development of the By-Pass Budget, the Institute also prepares a budget within the Administration's guidelines, policies, and funding levels. As a first step in this process a meeting is held with the Director, NIH, at which time the NCI Director presents the goals, accomplishments, and future directions of the NCI. Following this presentation, which emphasizes policy rather than specific projects, an Administration's budget is prepared within specific guidelines. The review process required for this budget involves modifications by the Director, NIH, Assistant Secretary for Health, Public Health Service (PHS), and the Secretary, DHHS.

Herein lies an important and substantial distinction between the two budgets: The By-Pass Budget prepared by the NCI with the professional judgment of outside advisory groups, by law, cannot be altered or modified by officials within the DHHS. However, the Administration's budget is prepared within the guidelines established at each successive level of review within DHHS. Both budgets are available to the President in September for his deliberations on determining the budget level that he will submit to the Congress in January as his request for the NCP.

Budget Presentation

In January, after the President submits his budget request to Congress, the presentation portion of the budget process begins. Between February and April, the Director, NCI, presents and defends the NCI portion of the President's Budget before subcommittees of the Appropriations Committees of both Houses of Congress. In addition, the subcommittees also hear testimony from outside witnesses regarding the NCP.

Following deliberations, the subcommittees and later the full Appropriations Committees "mark-up" the President's Budget request and provide funding levels appropriate to their program priorities and overall Congressional budget constraints. These funding levels are published in appropriation bills which must be approved by both Houses of Congress and signed into law by the President; thus NCI is provided with a budget, a process initiated 20 months earlier.

Budget Planning Process

Interlinked with the development of the budget is an internal NCI review cycle. As a part of the corporate decision-making process, the NCI Executive Committee has been constituted to include the Director, Deputy Director, Associate Director, Associate Director for Administrative Management, and the five Division Directors. Throughout the year, this body addresses major issues of management, resource allocation, and program priorities. As a further extension of this decision-making process, two Director's Meetings are held, one in January, the other in

[2] This section is based on material provided by the NCI Financial Management Branch.

July to make cross-divisional allocation decisions in planning for budget levels and operational decisions.

The January Director's Meeting establishes budget policy for future years with special emphasis on the next fiscal year. Operational plans for the current fiscal year are also reviewed. At the July Director's Meeting, specific divisional plans are established for the coming fiscal year. It is during this meeting that the advice provided by the NCAB and each division's BSC is coordinated into specific operating plans for the Institute.

Table 1 depicts the major steps and the degree of involvement of NCI staff, the NCAB, and the BSC in the budget process.

EVALUATION

Like planning, evaluation is accomplished as an integral part of program operations. Each program plan includes criteria suitable for the evaluation of program performance. The rigor of this process and the approaches used for performance evaluation are dictated by the type of program or activity to be appraised. For example, programs with quantitative objectives (training, construction, information systems) can be evaluated during the course of performance and upon completion, and the degree of success or failure in attainment of established objectives can be assessed at both times with a good degree of precision. However, for basic research efforts that are exploratory by definition and in which objectives are usually expressed in qualitative or subjective terms (e.g., elucidation of the mechanisms of action of certain viruses or determination of genetic sequences), evaluation is not as clear-cut. Beyond the initial assessment of scientific merit and promise accomplished by the peer review system, performance evaluation of basic research presents a unique set of problems. Because basic research efforts are exploratory and long-term in character, direction of effort may change several times during the life of the project, and substantive evaluation during the course of performance is usually not relevant. The evaluation of basic research is made even more difficult by the fact that any one of the following outcomes is considered a success: 1) Established objectives were attained, and the results contribute immediately to the solution of a particular aspect of the cancer problem. 2) Established objectives were attained, and the contribution of the results to the solution of a particular aspect of the cancer problem is not known immediately but must await future assessment. 3) Established objectives were not achieved, but the effort provided information or insight, or both, that will be useful to future research.

Typically, NCI evaluation activities deal with issues emerging from two levels of operation: either the national level or one with a specific program or program component. Aside from the Director and his staff, the individuals or groups responsible for performing these evaluations usually deal with only one of these levels. Although the President's Cancer Panel and the NCAB are primarily responsible for assessing the overall national effort, they may also review and assess the programs and operations of a particular NCI Division, e.g., the annual NCAB November program review discussed previously. The Director and Division Directors also initiate internal studies to evaluate performance in a particular program or administrative area in addition to those evaluation activities performed by officially established external groups. For example, the study and evaluation of the review procedures for intramural research which led to the development of the much improved peer review process now in place was an internal evaluation initiative.

At the national level, the concern is with the overall effectiveness of the total NCI effort and with the NCI's role as the lead Federal agency in the NCP. The Director, NCI, the President's Cancer Panel, and the NCAB each prepares an annual report assessing the overall effectiveness of the NCI program, including the description of progress and the identification of major problem areas and recommendations for solutions. National level evaluation activities are concerned with broad program directions, program "balance," or the relative investment of resources in the major areas of cancer research and control as well as with the overall effectiveness of NCI's management and its relationships with other Federal agencies.

At the program level, internal evaluation and evaluation performed by the divisional BSC are primarily directed toward the content, quality, and effectiveness of the major research and control programs from the perspective of achieving divisional goals and objectives. The identification of new leads and opportunities, the establishment or reordering of priorities, and budget requirements and shifts are determined on the basis of the results of these evaluations. The BSC also review and evaluate new divisional program plans before implementation.

In 1970, with the passage of P.L. 91-296, the Public Health Service Act (42 USC 299b) was amended to set aside up to 1% of the funds appropriated to any program authorized by the PHS Act or several related acts to be used at the discretion of the Secretary, DHHS, for the evaluation of health programs and associated activities. Most evaluation projects funded by this 1% have been retrospective in character, i.e., they were concerned with certain elements of programs that have been completed or with elements at a stage of development when evaluation is appropriate. Because such evaluations provide information essential to the planning process, evaluation criteria at both the project and program levels are frequently identified during the planning process. Some of these evaluation activities under this program during FY 1972–85 (projected) include:

FY	Funding	No. and type of project
1972–81	$1,740,781	13 completed
1982–83	713,000	6 ongoing
1984	1,947,000	7 new 3 continuing
1985	1,130,000	Continuation of those initiated in 1983–84; new ones may be added

Thus by the close of FY 1985, NCI anticipates that it will have completed evaluation projects for a total of

TABLE 1.—*Major steps in the budget formulation review process*

Responsible group	January and February	March, April, and May	June and July	August and September	October, November, and December
NCI Staff[1]	NCI Director's Meeting, establish overall budget policy for upcoming fiscal year, review operating plans for current fiscal year Submit Congressional justification for next fiscal year	Formulate preliminary budget for 2 years in future for both the By-Pass and the budget submitted within the Administrations' guidelines Congressional Testimony by Director, NCI	NCI Director's Meeting, establish specific division levels for upcoming fiscal year	Formulate By-Pass budget Formulate budget within Administration guidelines	Formulate President's budget
NCAB[2]		Review and revise preliminary budget for 2 fiscal years in the future		Review By-Pass (OMB) Budget submitted directly to the President	Hear presentations of program activities of Divisions for fiscal year just completed
NCAB Subcommittee on Planning and Budget		Meets with the Executive Committee to establish policy parameters for development of preliminary budget for 2 fiscal years in the future			
BSC[3]	Review operating plans for current fiscal year and policies from NCI Director's Meeting		Review and advise on implementation of specific divisional programs for current fiscal year	Present annual division budget reviews of current and future plans	

[1] Staff includes Executive Committee and key administrative personnel.
[2] Members of the NCAB are Presidential appointees.
[3] The BSC are outside NCI peer review bodies for each of four operating divisions.

$5,530,781 in funds that had been set aside. During FY 1972 to FY 1983, NCI was "tapped" $26,722,000 for the 1% evaluation fund.

COORDINATION OF THE NATIONAL CANCER PROGRAM

Coordination of the NCP by the NCI is mandated by the National Cancer Act. A variety of public and private agencies, organizations, and institutes involved in a broad range of cancer activities contribute to the achievement of the goals of the NCP. Because the NCI cannot direct or manage the activities of the other Federal agencies and the private organizations participating in the Program, its coordination responsibility essentially entails the development of a working knowledge of the cancer-related activities of these organizations so that collaboration and cooperation can be facilitated.

Coordination of the NCP can take many forms including interaction between top-level management and scientific program directors, and communication and information exchange between working researchers and scientist-administrators. Five different levels of NCI coordination activities are described separately for presentation purposes. However, in actual operations, effective coordination requires frequent interaction between participants and established feedback systems between all operating levels. This provides a high degree of return on the investment of time and effort in the form of improved program operations. A segmented and disjointed coordination process usually results in a minimum or no return on the investment of time and effort and sometimes can produce negative effects on program operations.

Coordination Within the National Cancer Institute

Within NCI, effort has been purposeful at all organizational levels (starting with the OD) to develop and sustain an effective process for coordination and information exchange. This effort has applied not only to the coordination of program activities which cut across more than one division, but also to the more effective linking of management and administrative activities throughout the Institute. The Institute has 3 major mechanisms for the promotion and maintenance of coordination and information exchange: regularly scheduled meetings of senior staff groups, a common program structure, and the Director's planning/budget conferences which include the senior program and administrative staffs of the OD and the operating divisions.

Meetings of Senior Staff Groups

Seven regularly scheduled meetings of specific senior staff groups are designed to effect coordination and information exchange as a basis for decision-making at the Institute management level. Additional meetings can be called by the Director or the Chairman of the respective groups as required. The membership of each group is shown in figure 2.3, and a brief description of the purpose of each group is as follows:

1) The *Director's Seminar* meets weekly and provides the Director with a science counterpart to the business, managerial, and operational aspects of other OD meetings. Reviews of promising scientific opportunities and leads are presented by invited speakers. Any problems, scientific or managerial, associated with the opportunity are also discussed at these seminars.

2) The *NCI Executive Committee* is the Institute's corporate decision-making body. It formulates Institute policy regarding program operations, overall management, and budget development; determines allocation of budget and resources including the preparation of funding plans for grants; and reviews the exceptions to these plans. Members review major programs in research, control, and resources development and advise the Director on reductions, expansions, terminations, and initiation of new program efforts within the context of the NCP.

3) The *OD Staff* meets weekly to advise the Director on general Institute policy and operations, including policies, programs, and budgets for areas of responsibility in the OD and the development of strategies for accomplishing the corporate decisions of the Executive Committee.

4) The *Planning, Evaluation and Legislative Staff* meets monthly to coordinate divisional evaluation and planning activities and the preparation of the Institute's major planning and evaluation reports, deal with related special issues and reports, and provide Institute positions and responses related to legislation and Congressional issues.

5) *Administrative Officers* exchange information, solve problems, discuss and develop administrative policy and procedures, and share advice about applying policies and procedures mandated by higher organization levels in their biweekly meetings. Occasionally, representatives of NIH-level service organizations are invited to discuss current issues.

6) The *Administrative Staff* Meeting is primarily for information exchange and transmission of business management policies, procedures, and news and includes summaries of NIH-level meetings, such as meetings of Executive, Personnel, and Budget Officers. Business management plans, policies, and procedures are discussed and developed, and problems are identified for resolution.

7) The *Extramural Business Staff* meets biweekly to discuss and develop policies and procedures affecting the business management of NCI grants and contracts. They also develop and oversee the information handling systems for managing extramural resources and activities and, as necessary, interact with the staffs of other NCI divisions.

Each division, as well as the OD of the NCI, has a Chief of Project Officers to monitor those aspects of contract activities which are the responsibility of the project officer. Each chief reports directly to the Division director, or in the case of the OD, to the NCI Director, and provides a centralized oversight of the project officer function. Meetings are held as required for discussion of specific issues or

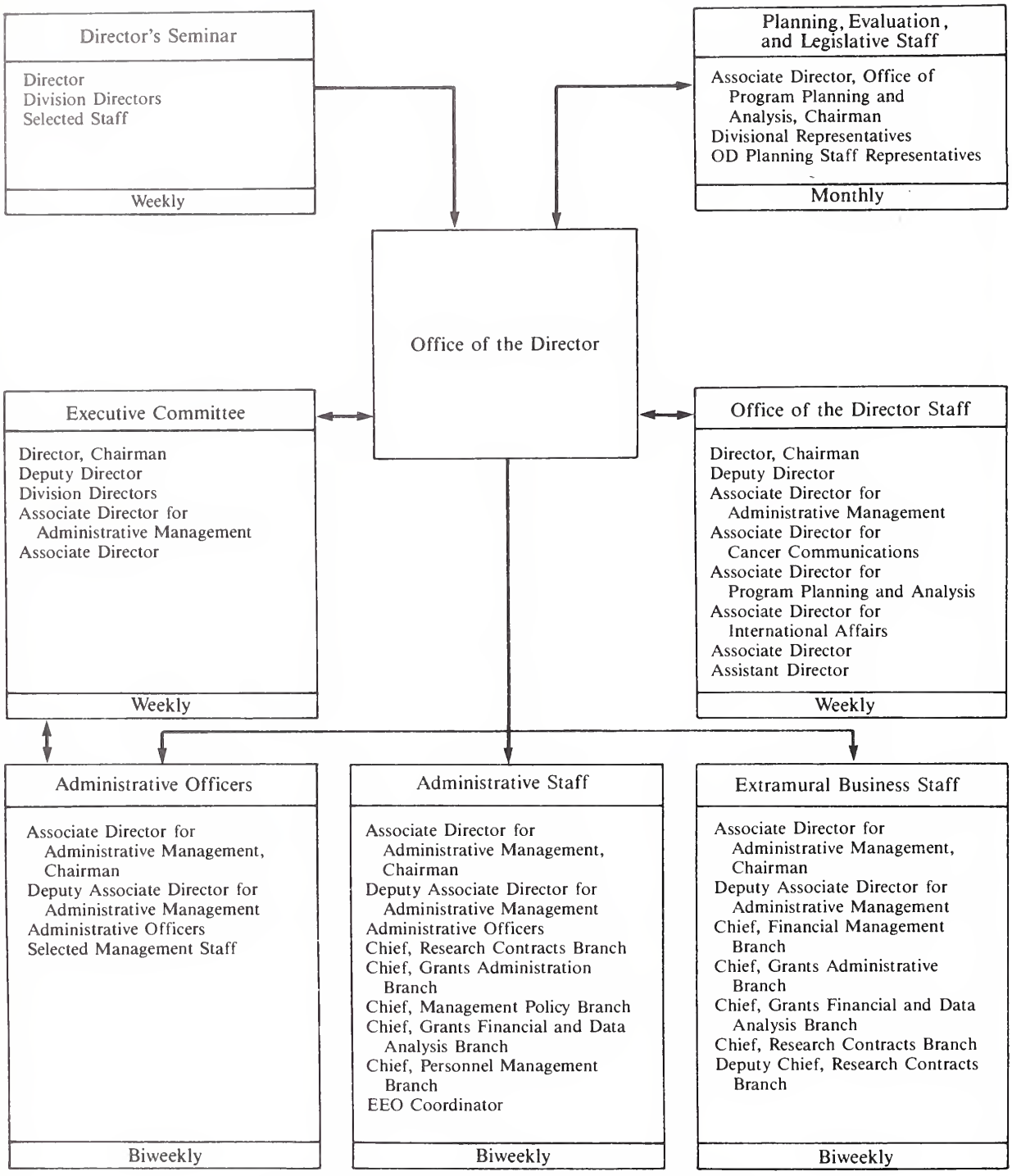

FIGURE 2.3.—Membership of Senior Staff Groups of the NCI.

problem areas related to this function, and recommendations are developed for problem resolution or improvements in the system.

Each of the four programmatic divisions has a Chief of Program Directors, who meets regularly with the Director of the DEA to aid in the coordination of the activities of the divisional BSC. At these meetings, members exchange information about program perspectives and projections, discuss NCI and NIH grant management, review policies, and take part in transdivisional discussions of extramural support issues. They serve as the divisional link for coordinating the activities of their BSC and for strengthening the BSC/NCAB interrelationships, and they transfer information about all extramural activities, both review and management, to their division's program staffs.

National Cancer Institute Program Structure

Mechanisms for coordination within the NCI are facilitated by the existence of a common program structure which identifies and defines the Institute's research, control, and resource development activities supported and managed by the divisions and in some instances by the OD. The acceptance of common program definitions facilitates coordination in program reviews, planning and implementation of new activities, priority judgments, allocation of resources, and budget preparation. The program structure is reviewed periodically by the planning and evaluation staff, the Divisions, and the Executive Committee to ensure that the definitions accurately represent current NCI program content and are acceptable to program leaders as a basis for decision-making in planning, budget development, and priority setting.

Director's Planning/Budget Meetings

Twice yearly, in January and July, the Director holds a meeting of the key divisional and OD administrative and program staff. These meetings are linked to the budget development cycle and are 2 to 3 days in duration.

In January, the operating plans for each division and the OD for the current fiscal year are reviewed and budget policy is established for the upcoming fiscal year. During March through June, preliminary budgets have been prepared in accordance with Administration guidelines, and the Director has testified before the appropriations committees of both Houses of Congress. This provides the basis for the July Director's meeting at which specific budget levels for the upcoming fiscal year are established for the OD and the operating divisions.

Although the primary orientation of these meetings is toward budget and other fiscal matters, agendas usually include other issues of current importance that demand some type of action, i.e., specific program problems or opportunities, space reallocations, new program developments, etc.

These meetings are intensive working sessions characterized by open and candid discussion and questioning of the issue under consideration. The merging of key scientific and administrative staff represents one of the most important and effective methods of coordinating Institute program and management activities and provides a forum for thorough discussion of major Institute policies before promulgation.

COORDINATION WITHIN THE NATIONAL INSTITUTES OF HEALTH AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

The NCI participates in the NIH Consensus Development Conference program, the purposes of which are evaluation of publicly available scientific data and information on either established or emerging biomedical technologies and production of a consensus statement that advances the understanding of the technology that will be useful to health professionals and the public. A broadly based panel of experts listens to the scientific data presented by other experts, weighs the information, and then develops a consensus statement that addresses a set of questions previously posed to the panel. This statement is an independent report of the panel and is not one of policy of the NIH or the Federal Government. Consensus development conferences are particularly useful for providing guidance when a controversy exists in differing therapeutic or diagnostic options and the issue is of public as well as professional interest. Since 1977, the NCI has sponsored 10 consensus development conferences either solely or in conjunction with other Institutes in a broad spectrum of sereening, diagnostic, and treatment subjects. In September 1983, the NCI and NIH Office of Medical Applications of Research cosponsored a Consensus Development Conference on Precursors to Malignant Melanoma.

The NCI is a member of the Coordinating Committee on Assessment and Transfer of Technology, which was established by the Director, NIH, to provide a mechanism for the coordination of NIH policy and activities related to health technology assessment and transfer. The Committee is composed of 1 representative from each of the BID plus the Associate Director for Medical Applications of Research, who serves as Chairman.

The Coordinating Committee has three major functions: It serves as 1) the principal forum for coordinating NIH's activities on health technology assessment, e.g., the planning of consensus development conferences and other meetings on technology assessment and transfer, the providing of consultative services to the PHS on questions of the safety and effectiveness of health technologies, etc.; 2) an advisory body to the BID, Office for Medical Applications of Research, and the Director, NIH, on policy matters related to the assessment and transfer of health technologies; and 3) a collegial body for mutual education and review of the various technology assessment and transfer activities conducted by the BID and Office for Medical Applications of Research.

The NIH Nutrition Coordinating Committee (NCC), established in 1975 to coordinate the nutrition research performed by the Institutes, has been expanded to include other DHHS/PHS agencies or liaison members. The NCC now includes: Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the Food and Drug Administration (FDA); Centers for Disease Control (CDC); the Office of Health Research Statistics and Technology

(OHRST); and the Health Resources Administration (HRA). The objective of the NIH–NCC is to facilitate the development of a comprehensive DHHS program in the biomedical and behavioral aspects of nutrition research and training.

Also, in the nutrition area, the NCI, several other Institutes of the NIH, CDC, National Institute for Occupational Safety and Health (NIOSH), and the Environmental Protection Agency (EPA) are collaborating in an epidemiologic study to identify human population groups susceptible to or at high risk of cancer to determine if there is a relationship between dietary habits and the subsequent risk of cancer.

The NCI staff serve on the NIH Acquired Immune Deficiency Syndrome Working Group which was formed to aid in controlling the current dramatic increase in this condition. The primary functions of the group are to foster information exchange among NIH and extramural staff and provide a ready channel for making current research findings available to the CDC and other agencies involved in controlling the disease.

The research programs on birth defects supported by many agencies of the DHHS (including the NCI, CDC, FDA, the Office for Maternal and Child Health, ADAMHA, and the National Center for Health Statistics) are being coordinated by the NIH.

The NCI is contributing to the National Toxicology Program (NTP) activities through an interagency agreement with NIEHS. Management responsibility for NTP was transferred from NCI to the NIEHS in FY 1981. Other agencies involved in the NTP are the FDA and NIOSH. The NTP serves as a focus for coordinating toxicology test development and testing among the relevant health research and health regulatory agencies. The NCI has representatives who nominate compounds for testing and serve on both the Chemical Evaluation Committee and the Executive Committee of the NTP. In addition to this Program, the NCI is involved with several other committees on toxic substances.

The NCI, with the NIH, ADAMHA, and FDA, serves on the DHHS Orphan Products Board. The group monitors, coordinates, and implements departmental activities in the area of drugs, chemicals, biologicals, and devices of limited commercial value but of significance in health and disease. The NIH provides FDA with scientific information about developments in the area of orphan drugs.

The Cooperative Minority Biomedical Program is a coordinated effort of the NCI, the Division of Research Resources, and the National Institute of General Medical Sciences. Awards are granted to minority institutions to develop programs to increase awareness among minorities of biomedical careers through the creation of greater opportunities for education; to involve an increased number of minorities in cancer-related research and training; and to support minority institutions and individuals in specific research programs.

In response to an increased public concern about radiation exposure, DHHS established a health research initiative and the Interagency Radiation Research Committee to coordinate activities on the biological effects of low-level ionizing radiation. As the lead agency, NCI provides major staff support for this initiative. Emphasis is on research leading to a clearer understanding of the risk of exposure to low-level ionizing radiation from natural sources, nuclear energy, industrial products, and medical procedures as a basis for recommendation for public health standards for human exposure. Cooperating DHHS agencies are: NIH, the Bureau of Radiological Health of FDA, NIOSH, and the Center for Environmental Health of CDC. The NCI also has a collaborative agreement with the FDA Bureau of Radiological Health for quality assurance in diagnostic and therapeutic radiation and has several interagency agreements with the Department of Energy related to the effects of low-level ionizing radiation.

COORDINATION WITH OTHER FEDERAL AGENCIES

Cross-governmental coordination is facilitated by the NCAB, which, in addition to representatives from the NIH and the DHHS, includes *ex officio* members from other Federal agencies: the EPA; NIEHS; FDA; the Department of Defense; the Office of Science and Technology Policy, Executive Office of the President; the Consumer Product Safety Commission; the Department of Labor; the Veterans Administration; and the NIOSH. Although these *ex officio* representatives cannot vote, they are encouraged to participate fully with the NCAB members in the discussion of all program, budget, and management issues brought before the Board. In addition, the NCI has active program collaborations with several Federal agencies.

The NCI and other Federal agencies are concerned with disease as it relates to environmental and occupational exposures. To promote coordination in this area, the NCI participates in the following collaborative efforts: with the Occupational Safety and Health Administration for the work hazard information program; with EPA to conduct studies of environmental causes of cancer in general and the human health effects of ozone depletion in particular; with NIOSH in studies on occupational carcinogenesis; with Department of Energy to develop 1) a report and data base on carcinogens and mutagens in drinking water and water affected by energy technologies and 2) training courses on environmental mutagens and carcinogens; and with CDC to conduct epidemiologic studies of cancer in Alaskan natives and of the consequences of polybrominated biphenyl contamination of farms in Michigan.

The NCI is a member of the Interagency Collaborative Group on Environmental Carcinogenesis, an informal committee, chaired by a representative of the NCI's Division of Cancer Cause and Prevention (DCCP). This group serves as a forum for an exchange of information among member organizations, the NCI, NIEHS, the Department of Agriculture, the Council on Environmental Quality, the National Oceanic and Atmospheric Administration, the National Aeronautics and Space Administration, the Department of Transportation, the National Science Foundation, and others involved in environmental carcinogenesis research and regulation.

The NCI participates in several committees concerned with smoking and health. The DHHS Interagency Co-

ordinating Committee on Smoking and Health was established to coordinate the Department's activities and to develop a research plan. Also, NCI is a member of the DHHS Working Group on Smoking and Heart, Lung, and Blood Diseases of the Interagency Technical Committee. This committee coordinates Federal smoking information and education programs. The following agencies are members: The NCI; National Heart, Lung and Blood Institute; Office of Personnel Management; Department of the Army; Department of Agriculture; National Institute on Drug Abuse; Office of Smoking and Health, EPA; National Aeronautics and Space Administration; NIEHS; Department of Energy; Department of Education; and the Health Services Administration.

COORDINATION WITH THE PRIVATE SECTOR

Within the context of the NCP, the NCI is extensively involved with the private sector in both coordinative and collaborative activities in information, education, epidemiology, and research projects in treatment and prevention. These activities are conducted with a broad spectrum of institutions and organizations including industry; labor; voluntary hospitals and clinics; medical, dental, and nursing schools; universities; and cancer centers.

Some of these activities in which the Institute is involved are given below:

The development of comprehensive cancer centers represents a major approach to coordinating efforts in the national program with public and private organizations. These centers, located around the country, conduct basic and clinical research, multimodality treatment trials, and cancer control activities. They serve as focal points for community involvement, continuing education of health professionals in cancer, research training, and for the sharing of cancer information with voluntary organizations, such as the American Cancer Society and the public.

The Surveillance, Epidemiology, and End Results (SEER) Program collects data on all cancer patients in 10 designated areas in the United States and Puerto Rico. Epidemiologists use these data to determine the national incidence, mortality, survival rates, and cancer trends. This Program also provides information for epidemiologic studies conducted by private and Federal agencies, e.g., the joint study by the NCI and FDA on bladder cancer.

The NCI has worked with labor organizations on the prevention and identification of occupation-related cancers. New Directions grants, funded by the NCI and Occupational Safety and Health Administration, have been used by labor groups to improve their ability to help prevent work-related cancers among their members through education, greater physician awareness, and better access to new information on carcinogens in the workplace.

Research projects are sometimes conducted or sponsored jointly by the NCI and private sector groups. For example, the NCI, E.I. Du Pont de Nemours, Inc., and the Formaldehyde Institute are conducting an epidemiologic study of the effects of exposure to formaldehyde; the American Cancer Society and the NCI have completed a 5-year screening program for breast cancer; and a joint study was conducted by the NCI, the Oil, Chemical, and Atomic Workers International Union, and NIOSH on oil refinery workers to determine the relationship between brain cancers and employment in oil refineries. In addition, a collaborative project between the NCI and Genentech, Inc. resulted in the first successful production of human gamma (immune) interferon through recombinant DNA technology.

The NCI provides the public, cancer patients, and the news media with accurate and up-to-date information about cancer through special information programs. The NCI/private sector link has been especially productive and successful in programs on smoking prevention and cessation, breast cancer, coping with cancer, pretesting health messages, and cancer communications networks. The private sector organizations provide financial and in-kind contributions, program design and development, technical assistance, promotion and distribution of materials, and evaluation of program effectiveness.

For example, the American Pharmaceutical Association, the Maryland Pharmaceutical Association, and the California Pharmacists Association collaborated with the NCI in the "Pharmacists Smoking Program." These associations provided financial support for the research and printing of test materials, technical assistance regarding smoking and drugs, and the pharmacists organizational network for distribution and communication purposes; they also helped to recruit pharmacists to participate in the qualitative research and materials testing. Similar cooperative and collaborative programs are being conducted in the other areas mentioned above.

Since the creation by the Congress of the Cancer Chemotherapy National Service Center in 1955, the NCI has established and maintained close working relationships with pharmaceutical and chemical companies. These relationships have involved informal collaborative working arrangements and formal contractual agreements and have made it possible for the NCI to play a role in the development or clinical evaluation, or both, of every commercially available antineoplastic drug in the United States.

The Biological Response Modifiers Program has established continuing relationships with several pharmaceutical and biotechnology companies which have an interest in supplying NCI with certain products for clinical trials or evaluation through our screening program. The companies and products have included:

Company	Product
Burroughs-Wellcome	Wellferon
Hoffman-LaRoche	Recombinant clone A interferon
Biogen	Recombinant gamma interferon
Cetus-Shell	Recombinant gamma interferon
Becton-Dickinson	Leu 2A monoclonal antibody
Hybritech	T101 monoclonal antibody

A good example is the well-developed and cooperative relationship between Burroughs-Wellcome and the NCI Program in the full evaluation of lymphoblastoid interferon (Wellferon) through phase I and biological response modifier trials. This agent will now be developed more fully by the Cancer Therapy Evaluation Program in several efficacy trials within cooperative groups.

These relationships and others have helped NCI obtain reagents for laboratory research and for evaluation of clinical trials. Most of these reagents have come to the NCI at no charge, and in turn the Institute has provided clinical information and laboratory results from the testing of these reagents. This reciprocal relationship has helped the companies develop their products and has greatly assisted the NCI in pursuing leads in new biologicals.

In some instances, private organizations will develop equipment for research or clinical applications and will request NCI to test the equipment under controlled conditions.

COORDINATION WITH OTHER COUNTRIES

Coordination is not confined to the United States. Collaboration with international organizations and with scientists from foreign institutions provides important information and insight on the different geographic, environmental, occupational, and social conditions of peoples throughout the world and the variations that have a critical influence on the incidence and types of cancer prevalent in a given area. The NCI shares in the international cancer research resources being used to support basic and applied research in the prevention, clinical management, and control of cancer.

The Institute participates in bilateral agreements with the following countries: Japan, Italy, France, Federal Republic of Germany, Poland, Egypt, Peoples Republic of China, Hungary and the U.S.S.R. These agreements provide for the exchange of scientists, specialists, technical information, materials, and in the organizing of collaborative research, international conferences, and joint publications. In addition, 17 nations currently are the recipients of NCI grants and contracts for the conduct of a wide variety of research activities.

The International Cancer Research Data Bank program facilitates the sharing of information about cancer with a worldwide audience through a computerized science information data bank and retrieval system. Widely attended international conferences, such as the 1980 International Conference on Aging and Cancer (a cooperative effort among the NCI, the National Institute on Aging, the House Select Committee on Aging, and two private foundations), are specific events that build international cooperation in health research. The NCI is also a member of two carcinogenesis working groups sponsored by the International Agency for Research on Cancer of the World Health Organization and is an active participant in the development and implementation of the programs of the International Union Against Cancer and the Pan American Health Organization.

During 1983, scientists of the NCI received a total of 274 visiting scientists, associates, and fellows, from 40 countries who came to the United States to engage in collaborative cancer research activities. Four of the visitors were appointed as experts and 59 came as Guest Workers, whose financial support was provided by sources other than the NCI. The activities of these visiting scientists were pursued in the laboratories of the NCI's Divisions of Cancer Treatment, Cancer Cause and Prevention, and Cancer Biology and Diagnosis. These associations have been mutually beneficial. The NCI host scientists were afforded opportunities to learn from their visitors about cancer problems in a given foreign country; about factors peculiar to that nation that might be related to the morbidity and mortality of cancer; and about activities underway toward the management, treatment, and prevention of cancer. Reciprocally, the foreign visitors were provided with unique opportunities to improve their mastery of the scientific method or to develop their potential for significant contributions to basic and clinical research.

The National Cancer Institute Contracting Process

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

CONTENTS

Foreword

The purpose of this document is to provide:

1) a historical accounting of the contract mechanism within the Public Health Service and the National Cancer Institute (NCI);
2) a description of the differences between the contract and grant as they are used in the research environment of NCI;
3) a description of the many activities associated with the three major stages of contracting: preaward, award, and postaward; and
4) a brief description of several recent audits of the NCI contracting process and some changes that have been made as a result of them.

This is a reference document for general purpose use and therefore does not replace nor should it be used in lieu of other official publications, applicable regulations, and executive orders relating to contracting or acquisition.

The National Cancer Institute Contracting Process[1]

Vincent T. DeVita, Jr., David M. Keefer, Louis M. Carrese, Bayard H. Morrison, III, and J. Paul Van Nevel[2, 3]

INTRODUCTION

The National Cancer Institute Act of 1937 created the NCI and designated grants-in-aid as the primary mechanism for the funding of work outside the Federal Government. This act also introduced Federal funding for training and for the establishment of fellowships. These activities remained small until after World War II.

Near the end of World War II, Dr. Vannevar Bush and others associated with the Office of Scientific Research and Development decided that wartime experience had demonstrated the value of strong Government funding of research and development activities and recommended that it should be continued in peacetime. The accomplishments of the Manhattan Project and the development of antimalarial drugs were cited as justification for such Government programs.

In addition, a number of important scientific projects were under way when the war ended, and it seemed unwise to discontinue them. It was decided, therefore, that existing Government organizations would take over the administration of these projects. The Office of Naval Research assumed responsibility for many of the projects in the physical sciences, and the National Institutes of Health (NIH) and the Public Health Service (PHS) for those in the biomedical field.

Because the Navy has for many years used contracts for funding research, projects in the physical sciences initiated during the war and afterward were funded by contracts. On the other hand, NIH and PHS, drawing upon their legislative authorities, used grants to fund biomedical research outside the Federal Government.

In 1955, Congress authorized the establishment of the Cancer Chemotherapy National Service Center (CCNSC), envisioning a directed and highly integrated multidisciplinary drug development effort with preclinical and clinical elements. It was an area in which not much interest was shown on the part of academia or industry. Dr. Kenneth M. Endicott agreed to head the program, but because of the extent of the research to be performed, the need to stimulate research, and the need to organize and integrate the research, he won permission to use contracts as a mechanism for funding.

From that point on, contracts have been used by the NCI as a major means of funding research and development efforts, in addition to the more traditional use of contracts to procure animals, materials, construction, etc. The Programs in Viral Oncology, Drug Development, Bioassay Testing, and the Immunology Programs, among others, have all used contracts extensively to stimulate work in these areas.

In 1962, a decision by NIH Director James A. Shannon excluded profitmaking organizations from competition for grants, so that support for these organizations was limited to the contract mechanism. Later in the 1960s, decisions were made that severely curtailed the support of [most] foreign projects through grant mechanisms, so that contracts were used to a greater degree in funding meritorious foreign projects.

Recently, NCI has used contracts as the mechanism best suited to stimulate major initiatives, including the Biological Response Modifier Program, chemoprevention, and high linear energy transfer treatment research. Such efforts require as a major emphasis the procurement of materials and equipment.

In the early 1970s, several reports were issued on the use of contracts in the research and development environment. These invariably resulted in changes in organizations or procedures, or both, to improve the use of the mechanism. The Section on External Examination in this chapter provides a brief synopsis of the most relevant reports.

In the late 1970s, the Inspector General, Department of Health, Education and Welfare (DHEW), and the General Accounting Office criticized certain aspects of NCI contract activities, primarily contract administration. These reports have been the catalyst for many NCI initiatives to improve the process. The Inspector General is in the final stages of his follow-up review.

The descriptions of the characteristics of contracts, the basis for selecting the contract as the instrument of support, and the review and administrative procedures associated with the contract depict the current form of the contract as it has evolved over a period of 25 years of use to satisfy best the particular requirements of the Department and NIH.

Whereas in many other Federal agencies, the contract has been the primary funding mechanism used in support of the full spectrum of activities from basic research to the purchase of supplies, the NCI has utilized two mechanisms

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[1] Previously published as National Institutes of Health Publication No. 82-2424; reprinted in September 1982.

[2] Office of the Director, National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health and Human Services, Bethesda, Maryland 20205.

[3] We acknowledge the help of many National Cancer Institute staff for the review of the earlier drafts and Mr. James Graalman, Chief, Research Contracts Branch of the Institute, and Mr. Carl Fretts, Director, Division of Contracts and Grants, National Institutes of Health, for review of the later drafts and technical advice throughout the preparation of this document.

to fund its various program activities: the grant and the contract. These mechanisms have been used primarily in the support or conduct of extramural activities, but in some instances are used for technical support or provision of resources to the intramural programs. With the passage of the Federal Grant and Cooperative Agreement Act of 1977, the use of a third funding instrument, the Cooperative Agreement, was authorized and the circumstances under which all three mechanisms were to be employed by all Federal agencies were formally defined. In the following sections, characteristics of each of these mechanisms will be discussed separately, including definitions, types, and uses, and the review procedures associated with each mechanism.

THE GRANT

Definition

The grant is a mechanism for providing funding assistance for the conduct of various activities including research, education, training, demonstrations, and conferences. The private sector is the initiator of the concept and the approach.

Although the degree of Government involvement varies with the type of grant, a general characteristic of the grant mechanism is that the funding agency exercises minimum control over the execution of the activity, i.e., operation of the Peer Review System by the Division of Research Grants (DRG) and assurance of compliance with administrative and fiscal policies. Therefore, the private sector grantee is accorded a great measure of freedom and bears the greatest responsibility for the success or failure of the project.

Types and Uses

As of October 1979, there were nearly 100 types of grants, all with carefully specified uses. Some could be used only by single agencies, e.g., P40 Animal Resource Grant Program, Division of Research Resources (DRR); D16 Grants for Start-up Assistance, Health Resources Administration (HRA), etc. The types of grants awarded by NCI (identified by activity code) are described below:

Research Project Grant (R01)

These grants are given by NCI to support a discrete, specified, circumscribed project of basic research to be performed by the investigator in an area representing his specific interest and ability. This is usually called a traditional research project. These grants are also used to support proposals solicited through the Cancer Research Emphasis Grant (CREG) and Request for Applications (RFA) mechanisms.[4]

Scientific Evaluation Grants (R09)

These grants provide the chairman of an initial review group (study section) funds for operation of the review group.

Clinical Cooperative Research Grants (R10)

These grants are awarded for support of prospective research activities (utilizing patient volunteers) for the assessment of the effect and value of various treatment modalities. Because the clinical resources necessary for the conduct of a major clinical trial are often not available at a single institution, a cooperative study is initiated which involves investigators in a number of institutions who are following a common protocol. The Cooperative Group Program is a component of the Division of Cancer Treatment (DCT). Personnel in DCT are responsible for monitoring and coordinating the grant-supported clinical trials, reviewing the treatment protocols, and analyzing the data therefrom. Beginning in Fiscal Year (FY) 1982, this program will be supported by the Cooperative Agreement mechanism.

Conference Grants (R13)

These grants are awarded to support national or international meetings, conferences, and workshops that effectively promote the goals of the national cancer effort.

Cancer Control and Rehabilitation Grants (R18)

Cancer Control and Rehabilitation Grants support rapid and effective application of cancer research findings in prevention; detection, diagnosis, and pretreatment evaluation; and rehabilitation and continual care. The purpose of the program is to identify, field-test, evaluate, demonstrate, and promote the widespread application of available and new methods for reducing the incidence, morbidity, and mortality of cancer.

New Investigator Research Grants (R23)

These grants support basic and clinical studies so that newly trained investigators can stay active during the early stages of their careers.

Clinical Cancer Education Grants (R25)

These grants are available to schools of medicine, osteopathy, dentistry, and public health, as well as to major affiliated teaching hospitals and specialized cancer institutions, for the purpose of improving and expanding education in the prevention, diagnosis, and treatment of cancer and the rehabilitation of cancer patients.

National Organ Site Program Grants (R26)

These grants are awarded to support planned programs of integrated laboratory and clinical research, which encompass a full range of investigative activity from basic research to experimental therapy focused on cancers of specific organs. There are four active National Organ Site Projects: Bladder, Large Bowel, Pancreas, and Prostate.

[4] The RFA is a technique used to stimulate or discern investigator interest in certain scientific areas. The division that plans to fund grants in a specific scientific field in support of specific initiatives must set aside a portion of its controllable funds that will be used to fund work in the area, should enough high quality applications be approved. Grants are awarded in priority order. However, if the funds set aside are not enough to award all high quality grants, the remaining grants are not necessarily funded (i.e., they do not go into the NCI grants "pool"). When grants that were initially funded in response to an RFA are up for renewal, they compete for funds with all other grants submitted to NCI. The RFA is supplanting the CREG, a mechanism used only by NCI that had essentially the same objective.

Program Project Grants (P01)

These grants support a broadly based, multidisciplinary, often long-term research program with a specific major objective or a basic theme. A program project, which generally involves the efforts of several large groups, is directed toward a range of problems having a central research focus, often linking preclinical and clinical research. These projects should constitute a system of research activities and projects directed toward a well-defined research program goal.

Exploratory Grants (P20)

These grants serve to support planning for new programs, expansion or modification of existing resources, and feasibility studies. Exploratory studies may lead to the development of specialized or comprehensive centers.

Cancer Center Support Grants or Core (P30)

These core grants provide support for cancer center elements required for the planning, development, evaluation, administration, and maintenance of an active and unified center that consolidates and focuses cancer-related activities in a single administrative and programmatic structure. The grants provide support for a core of professional staff, centralized services and resources, and shared equipment in development projects.

Cancer Research Facilities Grants (C06)

These grants provide matching Federal funds (up to 50%) for construction or major remodeling to create new cancer research facilities. In addition to basic research laboratories, this funding may include, under certain circumstances, animal facilities and/or limited clinical facilities that are an integral part of an overall cancer research effort. Funds for Cancer Research Facilities Grants are limited to $4 million total cost per grant, and the facilities constructed must be used for cancer research for at least 20 years. These grants may be converted to cooperative agreements in the future.

Postdoctoral Individual National Research Service Award (F32)

Grants of this type provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

National Research Service Awards for Senior Fellows (F33)

These awards provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

Research Career Development Awards (K04)

These are postdoctoral awards designed to promote the professional cancer research careers of individuals who are already scientifically productive and show promise of sustained future development.

Research Career Awards (K06)

These awards were developed to provide lifetime salaries for researchers who were scientifically productive and showed promise of sustained future development. No new awards have been made since 1964, and only one of these awards is currently being supported by NCI.[5]

Academic Awards (K07)

These grants are designed to stimulate research in education for cancer prevention in schools that do not have such programs and to strengthen and improve these programs in schools that do.

Continuing Education Training Grants (T15)

These awards assist professional schools and other public and nonprofit institutions to accomplish, expand, or improve programs of extensive continuation, extension, or refresher education dealing with new developments in the science or technology of the profession. This type of grant is applied in the development of training programs for veterinary pathologists.

National Research Service Award: Institutional Awards (T32)

These awards are made competitively to qualified institutions to develop or enhance training opportunities at the predoctoral or postdoctoral level. The applicant must have the staff and facilities for the proposed program. After the award is made, the institution's training program director is responsible for selecting the trainees and for administering the program. Residencies may not be supported by this program. Trainees are subject to service or payback requirements, or both.

National Research Service Award for Short-Term Research Training (T35)

This is a grant to provide individuals with research training during off-quarters or summer periods to encourage research careers or research in areas of national need, or both.

Cooperative Agreements (U01)

This instrument is used when an assistance relationship will exist between NCI and a recipient in which substantial programmatic involvement is anticipated between NCI and the recipient during performance of the contemplated activity. The Institute assists, supports or stimulates, and participates substantially with recipients in conducting projects similar in program intent to those for grants.

All grants are peer reviewed by chartered or ad hoc study sections, and those exceeding $35,000 in direct costs are also reviewed by the National Cancer Advisory Board (NCAB). An outline of the review process is provided in figure 3.1.

THE COOPERATIVE AGREEMENT (U01)

The cooperative agreement, like the grant, is a mechanism for providing funding assistance for the performance of a variety of activities. However, this instrument rather than the grant should be used when substantial involve-

[5] This type of grant has not been awarded since October 1979. As of September 1980, NCI was funding only one K06 grant.

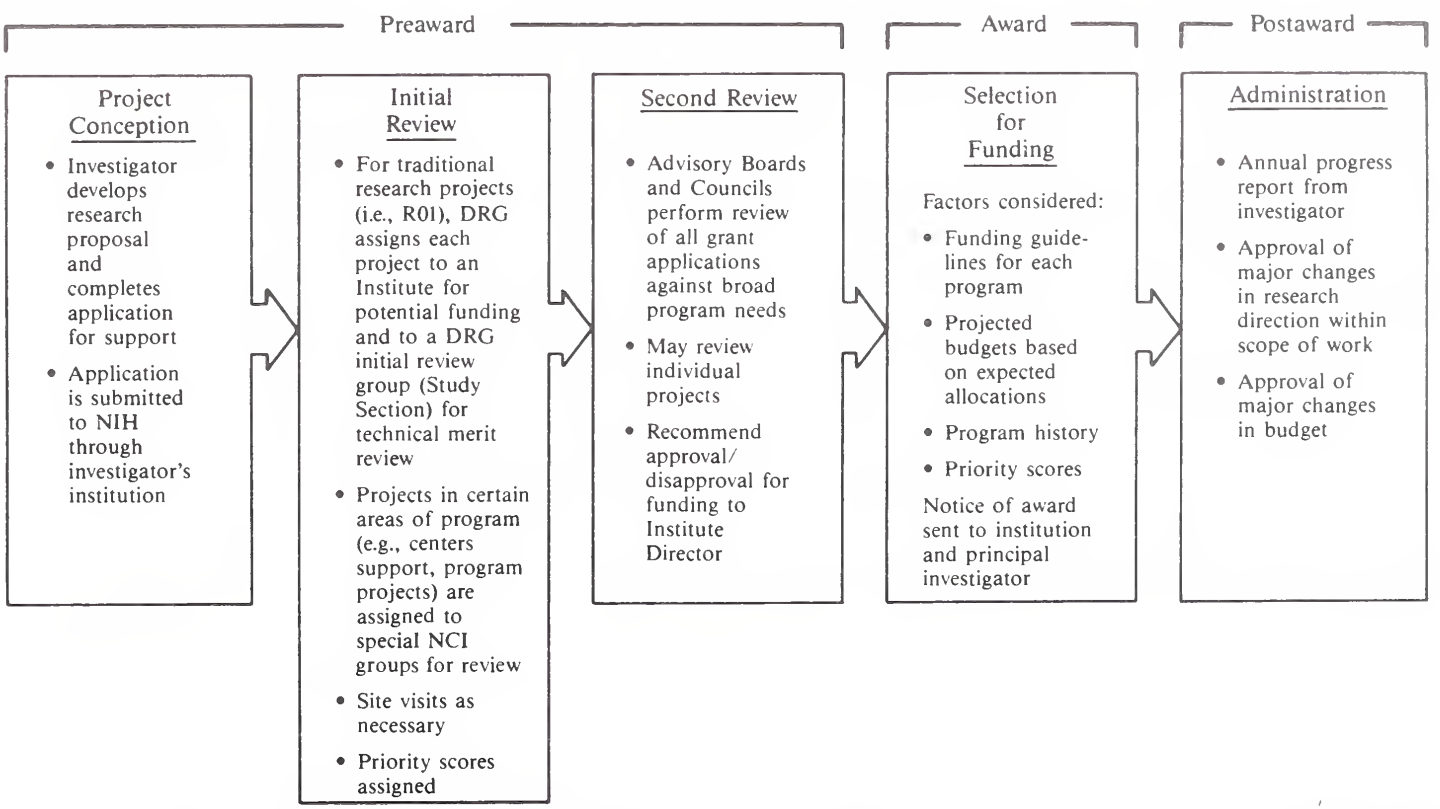

FIGURE 3-1.—Stages in the grant process. Although usually divisional BSC do not review individual grant applications, they are responsible for the review of a division's total program and the role of grants and contracts in the implementation of a division's program.

ment between the funding agency and the recipient is anticipated during performance of the activity. Under a cooperative agreement, a partnership is established between the Government and the private sector. The Government establishes broad guidelines for the research but leaves decisions on approach or methodology to the recipient. Certain terms, mutually agreed upon, and conditions clearly define and limit the Government's role. However, because the cooperative agreement is considered an assistance-type relationship, the initiative and primary discretionary authority rest with the recipient. Here support is given for the pursuit of knowledge in a broadly defined field identified by the Government. Thus the Government will not become involved in performing the work to be done, but, in accordance with the guidelines thus far established, may play a greater part in managing the project. For example, the relationship in spelling out a substantial degree of involvement may include:

1) agency power to define performance procedures and to halt the work if these performance measures are not satisfied,
2) agency review and approval of the work conducted in one phase of a project before work on a subsequent phase can begin, and
3) necessary conditions of agency and recipient collaboration.

The NCI has had no experience with this new instrument and departmental guidance is now in the formative stages. However, the review process for cooperative agreements will be similar to that used for grants.

The NCI plans to convert at least two types of grants to cooperative agreements: the R10, Clinical Cooperative Group Grant; and the C06, the Cancer Research Facilities Grant.

Clinical Cooperative Group studies (supported by grant or contract) serve as good examples of ventures, which, by virtue of Government and private sector involvement, qualify readily for support with cooperative agreements.

The NCI staff has a substantial programmatic involvement in the conduct of research clinical trials supported both by R10 grants and by contracts. This degree of involvement is necessary for a number of reasons: Because resources available are insufficient to permit exploitation of all identified scientific opportunities, NCI must carefully allocate resources (and monitor resource availability) to 1) assure study of the most important questions and avoid unnecessary duplication of research efforts; 2) assure that the limited supplies of investigational new drugs are distributed to groups in a manner that will put them to best possible use in the advancement of the state-of-the-art in cancer treatment; and 3) facilitate the close monitoring, reporting, and control that is required of NCI by the Food and Drug Administration in permitting the Institute to sponsor the clinical study of investigational new drugs.

A good example of the type and extent of staff involvement possible in cooperative agreements is the Clinical Cooperative Group Grants, by which NCI staff:

1) serves as an information resource regarding treatment regimen and clinical trial design;
2) assists the group in protocol design;
3) reviews all protocols which are developed by the cooperative groups and approves on a selective basis those involving investigational drugs and more than 100 patients [investigators may appeal protocol disapprovals to a clinical subcommittee of the Board of Scientific Counselors (BSC) of DCT that will serve as an appeals panel];
4) assists in the design of mechanisms for quality control, data management, and analysis;
5) approves mechanisms established for data management and analysis;
6) may determine when a protocol should be terminated (a decision that may be appealed);
7) has the option to crossfile or file independently on drugs evaluated under cooperative trials;
8) advises investigators of specific requirements concerning investigational drug management that the Food and Drug Administration may mandate; and
9) advises investigators of specific needs of the NCI drug development program to obtain clinical information and works as necessary with groups conducting clinical trials to develop the protocols required to obtain such information.

THE CONTRACT (N01)

Definition

A contract is a legally defined procurement mechanism, the purpose of which is the acquisition, generally by purchase, of property or services for the direct benefit or use of the Federal Government. Although the initiative for the concept arises from the Government, the actual scientific use of the instrument and the approach to the work may arise as a consensus of the scientific community. The negotiated contract used by NCI is awarded through a competitive process in which bidders are judged by reviewers on the basis of technical (scientific merit), business, and cost factors.

After award, the Government has a substantial monitoring involvement in the project which may range from tight control with a resource contract to general surveillance and support with a research contract.

Types and Uses

The Research Contract

In the research contract, the Government defines the specific area of research (e.g., treatment of breast cancer) and may identify general approaches, such as identification of a virus in cancer cells, development of a vaccine, or radiotherapy followed by chemotherapy for the treatment of a disease (*see* table 3.1).

The research contract is often used by the Government to stimulate work in an area that has been neglected by the private sector. The development of the research approach is left to the contractor, and his proposal is used by the technical peer review committee to judge his competence and understanding. Here the Government seeks a best effort situation in an endeavor to gain new knowledge.

TABLE 3.1.—*Characteristics of the research contract*

Specific areas of research and general approach sometimes defined by NCI, often with advice from outside sources
Proposal used by peer review committee to judge competence and understanding
Protocol development accomplished by contractor
Approval of major aspects of program the prerogative of NCI
Most often used to stimulate work in a neglected area

The work to be investigated and the limits within which the scientific investigation is to be conducted are well-defined and are more restricted than is found under a cooperative agreement. Final approval of all aspects rests with the Government during the course of the work.

The Resource Contract

In this type of contract, the Government establishes with greater precision an area of work, provides guidelines as to how the work is to be accomplished, and thus establishes a more specific "deliverable" result than is possible with a research contract (*see* table 3.2).

Resource contracts can be used for several purposes and can be classified according to the program area supported:

Extramural support

Resources.—Contracts may be designed to produce or acquire drugs, biological materials, or test data which are provided to grantees and contractors for use in their research programs. Rarely do these contracts provide for customized services (e.g., testing or screening) designed to respond to specific grantee or contractor requests.

Program development.—Contracts may be used to provide services, information, and materials that directly support an extramural program. Examples include the Drug Development Program in which contract support makes possible the synthesis, acquisition, preclinical testing, and dose formulation of candidate antitumor agents; and the Biological Response Modifier Program in which contract support facilitates the procurement and testing of candidate biological modifiers such as interferon.

Intramural support

Intramural laboratories also use contracts for support. These contracts may provide for specific end items, such as animal holding facilities, or they can provide for the performance of certain tests or laboratory procedures which are required to support the in-house research effort.

TABLE 3.2.—*Characteristics of the resource contract*

Specific area of work identified by NCI with advice from BSC
Precise specifications provided by NCI and incorporated in the Request for Proposal (RFP)
Contractor required to follow specifications
Most often used to acquire services and materials in support of a program

Equipment development

In some instances, the NCI will support the development of equipment required for the conduct of research. This is done only when the equipment is not available commercially or when no private firm is interested in its development either solely or in conjunction with the NCI. An example is the development of an ultrasonic imaging system designed to provide high resolution images of the thoracic and upper abdominal anatomy. A system which features an ultrasonic imaging transducer on the tip of an endoscope has been developed. In tests in dogs and human control subjects, the unit has provided clean images of many organs including heart, liver, kidneys, spleen, and pancreas.

Special Contract Uses

The Task Order Contract

The purpose of the task order contract is to make available several contractors who are able to perform specific activities designated by the Government. This arrangement provides for quick response to a specific requirement, makes accessible a pool of contractors with varied expertise, isolates costs for each project, provides flexibility for funding (funds are committed only as needed), and avoids prolonged contract competition once the master agreements are awarded.

The Interagency Agreement

This may be either a research or resource contract. The distinction is that the "contractor" is another Federal agency. The NCI has agreements with the Veterans Administration, Food and Drug Administration, Department of Agriculture, and several other Federal agencies.

The Prime Contract

The scope and complexity of some work require a number of contracts. Here the Government may select one contractor to be the "prime" with authority to monitor a number of subcontracts in such areas as technical performance, timely delivery, and coordination between the participating contractors. However, the Government makes all major program decisions and retains the senior management role, which is concerned with one instead of many contracts. As a result of some criticisms of their use and the increased difficulty of obtaining their approval, the number of prime contracts has declined and will probably continue to do so. Currently, NCI has one prime contract in force.

Pricing Arrangements

Government and the contractor can agree upon a number of pricing arrangements concerning various business and cost factors which become a part of the binding contract instrument. These arrangements include primarily such factors as establishment of the method of payment, reimbursement to the contractor, and the determination of the allowable fee (profit). Currently, the NCI uses four

TABLE 3.3.—*Pricing arrangements used by NCI*

Type	Definition	Remarks
Cost reimbursement	Payment of all allowable costs up to a limit specified in the contract during performance	Used with educational and nonprofit institutions when costs cannot be estimated accurately
Cost-plus-fixed fee	Cost reimbursement contract with a fee (profit) paid for performance of the work	Applied to commercial firms; certain nonprofit institutions eligible to receive fee but its use restricted for business purposes, no distribution to shareholders
Cost-plus-award fee	Cost-plus-fixed fee contract with incentive for additional fee	Fixed fee plus opportunity for additional fee based on a Government review panel's evaluation of performance
Firm fixed price	Firm price paid upon acceptance of each deliverable item	Ceiling prices with no adjustments; used when precise method of accomplishing work can be specified and is not subject to improvisation or change as work progresses

pricing arrangements in its contracting activities. The key features of the arrangements are shown in table 3.3.

SELECTION OF THE MECHANISM OF SUPPORT

Until recently, grants and contracts have been available to Federal agencies to establish necessary assistance and procurement relationships with outside organizations. Although the grant has been used to provide assistance and support in a fairly uniform manner, the contract has been employed in much more diverse ways and in some instances has been used by Federal agencies to meet all or most of the full range of agency needs for procurement and assistance.

With the implementation of the Federal Grant and Cooperative Agreement Act of 1977, the cooperative agreement became available as a second assistance mechanism, and the characteristics and uses of grants, cooperative agreements, and contracts were spelled out precisely. Although experience with agreements is limited, the Act and the Office of Management and Budget's implementing guidelines may permit varying interpretations. However, it is clear that NCI and all other Federal agencies now have two assistance mechanisms and one of procurement at their disposal. Thus the agency has a greater opportunity to select the funding instrument best suited to the characteristics of the work to be supported. Moreover, NCI has plans for the use of the cooperative agreement in the immediate future, e.g., to support cooperative clinical trials.

With the notable exception of CCNSC-sponsored research, the NCI used the grant to support virtually all extramural research until the mid-1960s. These efforts were primarily conducted by universities and nonprofit organizations. From the mid-1960s to the mid-1970s, with the development of large-scale national programs and the increased participation of private industry in NCI research programs that were not eligible for grant support, the contract was used to a greater degree to support extramural research efforts. Also, congressional mandates to supplement quickly several research efforts made the contract an ideal choice because, at that time, it was an efficient and expeditious way to procure a wide variety of activities that usually required less than 6 months for the entire procurement process.

During the last several years and for a number of reasons, the contract has been used to support basic research less and less, e.g., 1) new regulations which lengthen and complicate the procurement process, 2) criticisms of the administration of several of the steps in the procurement process, 3) questions concerning the quality and importance of the research supported by contract, and 4) NIH emphasis on maintaining a stable level of research grant support (R01 and P01).

It is reasonable for one to believe that use of research grants, submitted as a result of RFA solicitation, and cooperative agreements will provide instruments for research support that will both provide quality work and retain a measure of the precision and specificity in addressing important cancer problems.

Today, the choice of funding instrument rests primarily on the nature of the relationship to be established between the Government and the outside organization: Should it be assistance or procurement? For certain types of activities, the contract is the only appropriate mechanism: the procurement of animals, drugs, materials, etc.; the procurement of goods and services (including research) from other Federal agencies (the interagency agreement); and the procurement of goods and services (including research) from private, profitmaking organizations. The relationship between the type of work to be performed and the choice of the funding instrument is shown in table 3.4, and the predominant funding instrument based on project type is given in table 3.5.

Regarding the degree of Government involvement typically associated with the three funding instruments, the contract requires the most; the cooperative agreement permits variable degrees based on need (*see also* p 29), and the grant requires the least. These relationships are depicted below:

Relationship of funding mechanism to Government involvement

Degree of Government involvement		
← Lesser		Greater →
Grant	Cooperative agreement	Contract

TABLE 3.4.—*Typical characteristics of grants, cooperative agreements, and contracts*

Funding	Purpose	Project initiator	Detailed project definition	NIH program staff involvement
Grant	Assist, support, or stimulate research, etc.	Investigator	Investigator	Little or none
Cooperative agreement	Assist, support, or stimulate research, etc.	NIH	Investigator (within NIH guidelines)	Moderate to substantial
Contract	Procure specified service or defined end product	NIH	NIH	Substantial

Inasmuch as the Government involvement in contracts is solely monitoring, but it may include both monitoring and programmatic input in a cooperative agreement, the character of the government involvement in these instruments differs considerably.

THE DEVELOPMENT OF A CONTRACT

Introduction

The process of awarding contracts at the NCI requires a substantial amount of both staff and outside peer involvement. The review process for contracts involves three essential stages: preaward, award, and postaward. The preaward stage has three parts, i.e., planning, solicitation, and evaluation/selection (fig. 3.2). The solicitation part of the preaward stage and the negotiations conducted in the award stage are handled solely by the NCI staff. Outside peers and NCI staff are involved in other parts and stages of the process.

This section describes and defines the contracting process, including concept review, technical merit review, and NCI staff involvement. The major focus will be on the substantial change that has evolved in the review process itself. Also included are the key changes in contracting procedures that have contributed to the current elongated process.

Definitions

Concept Review

The first review in the contracting process is a determination of the basic purpose, scope, and objectives of the project in relation to the mission of the division. This is commonly referred to as "concept review" and for the sake of uniformity is conducted by each division's BSC. The law requires that the chairman and at least 75% of board members be non-Federal employees, but in practice membership of these boards is drawn almost entirely from non-Federal sources. Based on a knowledge of the division's mission, programs, objectives, budget, and resources, each board brings together the disciplinary expertise, which serves as the counterpart of that found within the division.

Each proposed project which first may have been conceived by advisers or staff is described at a meeting of a BSC. In reviewing a project, the Board considers the goals of the proposed activity and what technology and other resources are available to achieve these goals and makes recommendations depending on whether the:

project is consistent with the missions and objectives of the division;

purpose, scope, and objectives of the project have scientific merit;

resources to be devoted to the project are enough to accomplish its objectives;

suggested time is long enough to accomplish these objectives;

project could be suppported with a grant or cooperative agreement instead of a contract;

project is properly classified (as a resource or research contract, or a competitive/noncompetitive contract, or both); and

the priority level assigned a project should be high or low, given the total resources and competing activities of the division.

An NCI policy requires concept review of all contract projects including resource/support contract projects. Review of concept is required on all new competitive and noncompetitive contracts, all intra-agency and interagency agreements, and all renewals, including recompetitions of existing contracts and extensions that add $100,000 or more and extend the period of performance for 6 months or more. When projects are planned to encompass multiple contract awards, a single concept review is conducted for the entire project.

Technical Merit Review

Research and development proposals, submitted by the private sector in response to an RFP, are evaluated by a

TABLE 3.5.—*Predominant funding instrument based on project type*

Type of project	Funding		
	Grant	Cooperative agreement[a]	Contract
Fundamental research	Typically	(Choice)	
Applied research	Frequently	(Choice)	Typically
Development			Typically
General research support	Always		
Construction			
Extramural	Typically	(Choice)	
Intramural			Always
Materials (supplies, animals, drugs, etc.)			Always
Multi-institutional clinical trials	Choice	(Choice)	Choice
Technical support			Always
Training and education	Typically		

[a] The NCI currently has no cooperative agreements in force. Parenthetical entry is used to indicate project types for which this new mechanism could be used in the future.

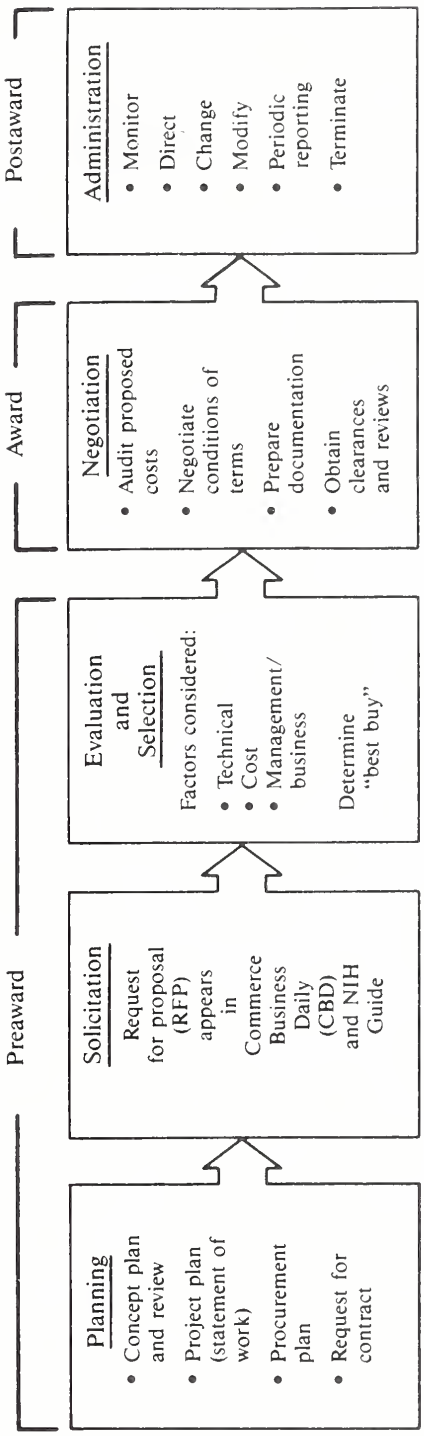

FIGURE 3-2.—Stages in the contract process.

peer review committee which must consist of at least 75% non-Government employees. These committees are under the administrative control of the NCI's Division of Extramural Activities (DEA), which is organizationally separate from the initiating division. At NCI, virtually all committees are staffed totally by non-Government individuals. Furthermore, these committees are chartered pursuant to the Federal Advisory Committee Act and their meetings are advertised in the Federal Register. (In exceptional circumstances involving single-meeting ad hoc reviewers, chartering is not required but meetings are publicly announced.)

The purpose of technical merit review is to get expert advice and consultation on the qualifications of the offeror's staff, the merit of his scientific/technical approach, the sufficiency of staff and institutional experience, and the availability of equipment and facilities. Each proposal is reviewed by the peer review committee, and the results of its deliberations are documented by an NCI Executive Secretary, who makes the findings of the peer review committee available to the contracting officer and project officer.

In performing its review, the peer review committee evaluates the following:

the contractor's understanding of the scope of the work and the Government's needs;
scientific or technical approach to meet these needs;
realism of the proposed time schedules;
availability of experienced scientific personnel, including their qualifications and professional experience, and the percentage of time they will spend;
adequacy and availability of necessary research, tests, and facilities;
accomplishments, developments, or pertinent ideas of the offeror in the specific branch of science or research involved; and the
offeror's willingness and ability to devote resources to the proposed work agreement.

Based on the findings and recommendations of the peer review committee, the contracting officer in collaboration with the appropriate program staff, determines with whom the Government will conduct negotiations. This determination generally includes all offerors who have demonstrated the ability to perform the contract project and who are, based upon the scoring and ranking by the peer review committee and the proposed cost, competitive with other offerors. These negotiations consist of discussions of the business/cost proposal and on any ambiguities, deficiencies, or weaknesses noted in the proposal by the peer review group. Offerors are given an opportunity to revise their proposals, which are then reviewed by an ad hoc committee of program staff. Sometimes, the revised proposals are reviewed by the original peer review committee.

Staff Involvement in Preaward Review Process

Most of the concepts behind contract development do not originate with NCI staff members; rather they are the result of interaction between staff and members of the scientific community. Concepts may come from several different sources (workshops, seminars, consensus committee recom-

mendations, and ad hoc groups of consultants). In many instances, the concept may result from work which has been completed under a previous contract or grant or from recommendations from the BSC.

Nevertheless, NCI's scientific program management and contracting staffs play major roles in the contracting process. Members of the scientific staff of the sponsoring division have the primary responsibility for preparation of the concept paper, the statement of work, and the evaluation criteria. Their consultation with the senior management staff and contract specialists in the division is critical to the successful and timely execution of the contracting process.

After identifying a new concept, the scientist who will serve as project officer will develop a brief concept paper that will be circulated to staff for review and comment. A recent change in the review process dictates that, if enough interest is generated within the division, the concept will be presented to the BSC for review and recommendation of approval or disapproval to the Division Director. The project officer describes the merits of the proposed project to the Board.

If a concept is recommended by the Board for approval, the project officer, consulting with the contract specialist and with other representatives of the division, prepares the statement of work and the evaluation criteria. The documents are then incorporated into a project plan, which is the official request for contract. In a procedure new for most divisions, this document is presented to the division's senior scientific and management staff for review, comment, and approval. The final version is incorporated by the contracting officer into the RFP.

The project officer also attends the technical review of the proposals that are submitted in response to the RFP and assists the contract specialist in negotiations. At the technical merit review meeting, the project officer, although considered an information resource, is not allowed to make evaluative statements about the proposals. When negotiations are held, the project officer assists the contract specialist in preparing questions for the offerors. He makes certain that all weaknesses, ambiguities, and certain deficiencies noted in the technical merit peer review are provided to the offeror for response. He also evaluates the judgmental direct costs included in the cost proposal, and his comments are provided to the contracting officer and Government cost auditor for consideration in analysis of the business proposal.

THE CONTRACTING PROCESS: PAST AND PRESENT

Over the past 25 years, the contracting process within DHEW (now the Department of Health and Human Services, DHHS) has undergone significant change. Although most of the changes have improved some aspects of the process, each change has also added time to the execution of practically each step in the process. Probably the most important changes promulgated by NCI have resulted in the greater participation of outside scientists and advisers in the review aspects of the procurement process and in the evaluation of contract performance as a part of overall program planning and budget responsibilities, now assumed by the BSC of several divisions.

Historically, the many changes in the contract program can be grouped into 4 periods to reflect the current process: 1956–70, 1971–73, 1974–79, and from 1980. These changes are highlighted in table 3.6 and are discussed in more detail below.

First period: 1956–70

The negotiated research contract was first used by NIH in 1956 in conjunction with the CCNSC Program of the NCI.

In subsequent years, other NCI program areas, e.g., viral oncology, adopted the contract mechanism to support research and resource development. From the mid-1950s until the early 1970s, the procedures required to use this mechanism were simple and rapid.

1) The entire contracting process was performed almost exclusively by NCI staff with limited input by outside consultants.
2) Concept review as currently defined did not exist. Project planning, RFP development, and determination of relevance, priority, and need were performed almost entirely by NCI staff.
3) In competitive procurements, *technical merit review* and *contractor selection* were performed by NCI in-house program committees. Outside advisers participated only at the discretion of program leaders.
4) Single source awards to the educational institutions could be made without competition.
5) Upon completion of in-house technical review, a *contract could be awarded* following negotiations between the contracting officer and the selected offeror.
6) The procurement process from planning to award took less than 5 months.
7) Postaward administration was an NCI staff responsibility. Upon the discretion of program leaders, intramural or non-NIH peers were invited to participate in ad hoc evaluations of contract status and contractor performance. Such evaluations were usually conducted as a part of program reviews.

Second period: 1971–73

The early years of the 1970s saw the introduction of the first of various regulatory and procedural changes that have served with later changes to alter radically a basically uncomplicated system. Each of these changes increased the complexity of the procurement (contracting) process and added to the time required for its completion.

> "Competitive range" negotiations were mandated in 1970 in HEW Procurement Regulations which limit selection of a contractor on the basis of evaluation of initial proposals to special circumstances. They required that those whose proposals were deemed to be in the competitive range (i.e., those with a reasonable chance for award) be allowed after proposal clarification and correction of certain deficiencies to improve their proposals and submit "best and final offers." The

TABLE 3.6.—*Highlights of changes in the contract process: 1956–80*

Period	Preaward		Postaward monitoring and evaluation	Examples of programs utilizing contracts initiated during the period
	Concept review	Technical merit review		
1956–70	Concept review as currently defined not in existence, development of proposals for research and resources contracts and determination of need, relevance, and priority performed by NCI staff	Technical merit review performed by NCI staff with outside staff involvement at discretion of Division Director, usually on individual scientist basis		Cancer Chemotherapy National Service Center Viral Oncology Chemical Carcinogenesis Breast Cancer Task Force Less Hazardous Cigarette
1971–73	Concept review and merit review separate Outside peer involvement optional Composition of review groups predominately outside scientists Research contracts only Resource contracts still reviewed by NCI staff	Equivalent of merit review performed by NCI staff for research contracts Peer merit review at discretion of Division Director Some chartered review committees established	Primarily NCI staff responsibility with periodic ad hoc evaluations of contract performance (usually as part of program review) by Extramual and Intramural peers at option of Division Director	Immunology International Cancer Research Data Bank Cancer Control Surveillance, Epidemiology, End Results (SEER)
1974–79	Concept review mandatory as per NIH guidelines Review committees predominately extramural scientists All Divisions appointed BSC but used differently Use of concept review of R&D and resource contracts by DCT/BSC Use of intramural review of research and resource contracts by other divisions	Mandatory peer review of technical merit of R&D contracts by chartered review committees composed of predominately extramural scientists Resource contracts reviewed by NCI staff		Neutron Generator Nutrition National Toxicology Program Biological Response Modifier Cancer Centers Patient Data System
1980	Mandatory concept review by BSC for all Divisions of both research and resource contracts; OD contracts reviewed by subcommittee of the NCAB	Mandatory peer review of research and resource contracts by chartered committees composed predominately of extramural scientists Administration of technical merit review of all contracts (Divisions and OD) responsibility of DEA	Evaluations of contract performance by Divisional Boards as part of their overall review responsibilities; also for contract renewals over $100,000 and extensions of 6 months or more	None

evaluation of these best and final offers then becomes the basis for contractor selection. This process adds a minimum of 30 to 45 days to the contracting process. In 1972, HEW authorized NIH to decentralize its contracting operations to NCI and several other Institutes. At the same time, a centralized Board of Awards was created. This board had to review all NCI contracts over $750,000, a process which added 10 to 15 days to the contracting process for about 25% of the Institute's contracts.

During this period, NCI began to involve non-Government scientists to a modest degree in some phases of the procurement process.

Concept review, an evolving technique, was not yet a formally articulated function. Division Directors to a variable degree began to exercise their option to involve divisional advisory bodies (composed primarily of non-NIH scientists) in this and other presolicitation phases of the research contracting process (e.g., project planning).

Some chartered committees were established.

Technical merit review of research contracts was performed largely by NCI staff, although outside committees participated in this activity at the discretion of Division Directors.

The responsibility for all phases of the procurement of resource contracts was retained by NCI staff.

Postaward contract administration remained the responsibility of NCI staff.

Third period: 1974–79

From the middle 1970s to 1980, the provisions of a number of additional laws, regulations, and procedural changes were put into effect.

In 1974, amendments to the National Cancer Act required that research and development contract proposals be subject to peer review by groups composed of not less than 75% non-Federal employees. For proposals involving innovative and original approaches, a double peer review is required of concept before RFP development and of proposals submitted in response to the RFP. The logistics of organizing and conducting these reviews adds 30 to 60 days to the contracting process.

Since the late 1970s, great emphasis has been placed on awarding contracts to small businesses including organizations that are socially and economically disadvantaged. Accordingly, every NCI project that is to be contract-supported must be screened by the Small and Disadvantaged Business Utilization Specialist in the Research Contracts Branch (RCB) to determine if the work can be conducted by small business, minority- or women-owned businesses, or an organization in a labor surplus area. This screening process can add weeks to the procurement cycle.

In 1977, HEW implemented a number of initiatives to tighten up contracting procedures in the department. These involved establishment of new clearance, approval, and reporting requirements. These more rigorous requirements can add as much as 60 days to the contracting process.

In March 1979, major changes took place in the area of noncompetitive procurements, i.e., those situations in which the Government program staff believes that one offeror is a best and uniquely qualified "sole source" for the procurement.

Before March 1979

Each NIH bureau, institute, and division (BID) had "signoff" authority for sole source procurements up to $100,000.

The NIH had unlimited signoff authority in the dollar levels of sole source procurements.

After March 1979

Each BID has signoff authority for procurements up to $25,000.

From $25,000 to $100,000, signoff is by the NIH Division of Contracts and Grants.

From $100,000 to $500,000, signoff is by the Director, NIH.

Over $500,000, signoff is by the Assistant Secretary for Health.

Other mandatory steps have been added to the procurement process since the middle 1970s. These include preaward clearance of NCI contracts greater than $1,000,000 by the Office of Federal Contract Compliance Programs, Department of Labor, to insure that the contractor has an approved Affirmative Action Plan. In 1979, the Congress passed Public Law 95-507, which requires a plan for subcontracting to small and disadvantaged businesses as part of all contracts exceeding $500,000.

During this period, these requirements and changes introduced by NCI produced significant changes in the balance of staff and adviser involvement and responsibility in the procurement process.

All divisions established BSC but did not uniformly designate their functions.

Concept review of contracts was mandated by NIH.

The BSC of DCT was given the authority for concept review of research and resource contracts. The advisory group of the former Division of Cancer Control and Rehabilitation (DCCR), which is now a part of the Division of Resources, Centers and Community Activities (DRCCA), was given similar authority. More recently, the BSC of the Division of Cancer Cause and Prevention assumed responsibility for concept review of research contracts.

Except for DCT, NCI staff retained the responsibility for all phases of the procurement of resource contracts. The DCT staff retained responsibility for all but the concept review step.

Technical merit review of Research and Development (R&D) contracts by chartered outside peer review committees became mandatory.

Technical review of resource contracts is conducted by NCI staff.

With two exceptions, *postaward contract administration* remained totally the responsibility of NCI staff. Through the technique of "merit review" of ongoing contracts, DCCR accorded outside advisers a measure of responsibility in contract monitoring and evaluation. The BSC of DCT, by assuming a responsibility for concept review, took a role in program review and evaluation in which contract performance is a factor.

Fourth period: 1980

Differences still exist in the divisional handling of planning, evaluation, and postaward administration of contracts. However, this is a period of transition in which all divisions as well as the Office of the Director (OD) are to implement mandated methods for all phases of the procurement process. This will bring a much needed and desired uniformity to the NCI contracting process.

Concept review of research and resource contracts by the divisional BSC and for offices under the OD by a subcommittee of the NCAB is mandatory.

Technical merit review of research and development and resource contracts by chartered or ad hoc committees (predominantly non-Federal scientists) is mandatory.

Technical merit review of all contracts (divisional and OD) is to be administered by the DEA.

In the area of *postaward administration,* divisional BSC will 1) perform evaluations of contract performance (as a function of program review) and 2) review performance and concept of proposed contract renewals (extensions adding $100,000 or more and extending the performance period for 6 months or more).

Prior to 1970, the NCI could award a contract in 6 months or less. Due to all the changes described above, it now takes 9 to 12 months, starting with concept review. Table 3.7 shows the chronology of the steps involved and their approximate lead times. Because much of the additional time is required for the review process, NCI may be able to reduce lead time by improved planning and coordination.

NATIONAL CANCER ADVISORY BOARD REVIEW OF CONTRACTS

Considerable discussion has ensued on the degree of involvement of the NCAB in the contracing process, and several options for this involvement have been proposed for NCI staff and discussed at meetings of the Board. The following motion was passed at the November 1980 meeting of the NCAB which expresses the Board's position on this matter.

"In order to facilitate interchange between the National Cancer Advisory board and the boards of scientific counselors of the divisions of the National Cancer Institute and to enhance the capabilities of the NCAB to carry out its mandated responsibility of monitoring programs and recommending policy of the National Cancer Plan to the Director of the NCI, the following recommendations are presented to the Director for formulation beginning in 1981:

TABLE 3.7.—*Steps in the NCI contracting process*

Activity	Responsibility	No. of days	
		Specific action	Cumulative
Concept review	Board of Scientific Counselors		
Project plan approval	Research Contracts Branch Section Chief/Division Director	14	14
CBD/NIH Guide notice published	Contract Specialist	14	28
RFP issued	Contract Specialist/Contracting Officer	14	42
Proposals received	Contract Specialist	45	87
Technical evaluation	Division of Extramural Activities	45	132
Preparation and distribution of minutes	Executive Secretary	10	142
Review of minutes and revision (if necessary)	Contract Specialist/Executive Secretary	14	156
Source evaluation group review	Contracting Officer/Project Officer	10	166
Competitive range determination	Contracting Officer	7	173
Written/oral discussions	Contracting Officer/Project Officer	10	183
Receipt of best and final	Contract Specialist	14	197
Review of best and final	Source Evaluation Group	14	211
Source selection	Research Contract Branch Section Chief/Division Director	7	218
Audit of cost proposal	Division of Contracts and Grants	30	248
Final negotiation	Contract Specialist	14	262
Documentation	Contract Specialist	14	276
Review of files	NIH Board of Awards/Division of Contracts and Grants	14	290
Contractor signature	Contractor	7	297
Award	Contracting Officer	5	302

"(1) Chairpersons of the boards of scientific counselors (BSC) or their designates are invited to attend all meetings of the NCAB and its subcommittees and shall attend the November meeting of the NCAB and participate in the program reviews at that time. At this meeting, each chairperson will report on the year's activities of his/her BSC."

"(2) Copies of the minutes of each BSC meeting and those of their subcommittees shall be forwarded to all members of the NCAB as soon as they have been drafted. The activities and policy recommendations of the BSC's should be clearly delineated in such minutes. These will be given the most serious consideration by the NCAB in decisions on policy and program. A standing invitation for members of the NCAB to attend the meetings of the BSC's has been given by the Director."

IMPROVEMENTS IN THE NATIONAL CANCER INSTITUTE CONTRACTING OPERATIONS

In recent years, the NCI has initiated several major steps to improve its contracting activities, an ongoing process resulting from evaluations conducted by internal and external groups. Major changes in the review process are described in the preceding section and additional improvements are described below.

Separation of Proposal Review from Program

Before May 1978, the NCI operating divisions were responsible for the peer review of all contract proposals. Although these committees were constituted within the guidelines of the Federal Advisory Committee Act and the Peer Review Regulations, it was determined that because the executive secretaries and the committees were administratively responsible to the Division Director, the strict objectivity of the review process might be questioned.

Therefore, in October 1978, the responsibility for the review of all research and development contract proposals (but not resource contracts) was assigned to the then Division of Cancer Research Resources and Centers. This was part of an Institute-wide reorganization that resulted in a new DEA, which is now responsible for all proposal reviews. The committees and executive secretaries involved in the process are also assigned to the DEA. This action placed all peer review of technical merit in a division separate from the divisions with direct program responsibilities. It established independence for the peer review groups and resulted in one uniform approach to peer review in contrast to the various methods used in the past.

Changes Within the Research Contracts Branch

Steps were also taken by NCI to improve the organization and operation of the RCB. Some of the more recent improvements are listed below:

Centralization of the Research Contracts Branch Staff

Since its inception, RCB staff members have been located with the program areas they supported. This was considered the most effective way the partnership of project officer and contract officer could be accomplished, a partnership essential to the success of the contract process. However, this has caused other problems within RCB. Because the Office of the Chief, RCB, was physically separated from the contract specialists, the chief's ability to provide the level of direction and supervision needed by the staff was hampered, particularly in the area of contract administration. By mid-October 1980, NCI had centralized geographically the entire RCB. This centralization is expected to foster better management of the workload and of the staff, more effective contract administration, and improvement in the training of contract specialists.

Emphasis on Contract Administration

As a result of the Civil Service Reform Act, managers and executives will be evaluated for merit pay on critical job elements. The Chief, RCB, has advised his section chiefs and team leaders that contract administration will be an important item in performance appraisal. In addition, the Chief has established a Contract Administration Review Team which is responsible for auditing the quality of contract administration within RCB. This team is under the direct supervision of the Deputy Chief, RCB, and is led by a senior contract specialist. This first review was completed in August 1980 and within the next 12 to 15 months the performance of each contract specialist within RCB was to be reviewed.

The results of the team's findings will be presented to the Chief, RCB, for consideration. It is expected that, when justified, unfavorable reports will be considered in merit pay evaluation.

In addition to contract administration reviews, the Office of the Chief has established a retrieval system for the information related to the reviews of all contracts assigned to each contract specialist in the Branch. As of October 1980, RCB can retrieve comments by the RCB Review and Approval Officer and the NIH Board of Awards for every action over $500,000 for the past 2 years. This information will be available for training and evaluation.

Review Procedures

Additional emphasis will be placed on the review and approval of certain contractual documents. In the past, contracting officers have had significant authority in the area of project plans, justifications for noncompetitive procurements, competitive range determinations, and source selections. Sometimes, the authority delegated to the section level may have led to certain action decisions without consultation with the Office of the Chief. As of October 1, 1980, the number of RCB staff with approval authority was reduced (in many instances by as much as one-half) for more effective direction and leadership.

EXTERNAL EXAMINATION OF NATIONAL INSTITUTES OF HEALTH/ NATIONAL CANCER INSTITUTE CONTRACTS

Background

The use of contracts in the biomedical research environment has been the subject of many examinations since 1962. Most of these examinations addressed the use of

contracts to obtain research, the management of contracts and grants in biomedical science, and the staffing of organizations to enhance the quality of targeted research. Of primary interest are those studies which affect overall policy and operation. The following reports are worth noting:

Report to the President on Government Contracting for Research and Development

The Bell Report (1962) was on the study that examined general Federal policy regarding the Government's use of the contracts to private institutions and enterprises to obtain research and development work needed for public purposes. Those who submitted the report supported both the mutual benefits of the "partnership" between Government and private institutions and the strengthening of public research and development agencies, so that extramural activities could be managed. They also endorsed peer review and nongovernment advice in science programs, even when Government staff are competent to evaluate the scientific aspects.

Biomedical Science and Administration: A Report to the President

The Woolridge Committee (1965) considered contracts and grants interchangeably and recognized that both were research support mechanisms. This Committee expressed concern over the scientific quality and propriety of those activities supported by contract. The NCI Cancer Chemotherapy Program and the Collaborative Perinatal Project of the National Institute of Neurological Diseases and Blindness (now the National Institute of Neurological and Communicative Disorders and Stroke) were singled out. It was recommended that the NIH keep collaborative programs as small as possible, allow "contracting out" for project coordination and analysis, and establish a firm policy that no collaboration program be initiated unless a "strong management team" is established.

Report of the Secretary's Advisory Committee on the Management of the National Institutes of Health Contracts and Grants

The Report of the Ruina Committee, established to study the distinction between grants and contracts, the nature of administrative arrangements necessary to assure proper use of grants and contracts, and the circumstances surrounding current and prior use of contracts at the NIH was submitted in 1966. The Committee assumed that new knowledge stemming from increased basic research efforts would increase the opportunities for realistic programs targeted to the application of knowledge. The members made several specific recommendations for strengthening the management of targeted research: 1) that grant research be continued and protected from "encroachment of problems attendant on the increasing need for the NIH to embark upon programs of directed research or development"; 2) that proper staffing policies and practices, organizational structures, and management mechanisms be developed to enhance the quality of targeted research; and 3) that National Advisory Councils, although not responsible for review of individual contracts, should review and comment upon the overall programs of their respective institutes, including targeted research programs. The Committee also noted the difficulty of mounting targeted research and development programs by contract in a field of science in which the clientele were familiar and comfortable with investigator-initiated activity supported by grants.

Review of Research Contracts at the National Institutes of Health

The Sisco Report (1969) represents the conclusion of an evaluation of contract management operations at the NIH. The team conducted both an audit of selected contracts and a survey of research contract operations. They found that the NIH's contracting practices were in compliance with law and regulation, but the organization of the contract management responsibilities was improper for a program of the diversity, scope, and magnitude of the NIH. As a result of the specific recommendations, authority to negotiate and award contracts was delegated in 1971 to those NIH Institutes with large contract programs.

Report of the Ad Hoc Committee to Review the Special Virus Cancer Program

The Zinder Report (1973) of a study requested by the NCAB was critical of the quality of peer review and the appearance of conflict of interest on the part of reviewers and program managers. A restructuring of the review groups to include more non-Government scientists and to lessen the influence of the NCI members was recommended. In addition, the Committee recommended that all contract projects be open to competitive bidding within 3 years. They closed with a statement of concern over what was perceived as the "erosion" of the support base of fundamental science.

Report of the NIH Program Mechanisms Committee

The Cooper Committee Report (1973) is one by a committee established by the NIH Director to "review the means and methods used in formulating and administering programs at the NIH." This group developed its recommendations around the assumption that the "goals of the agency should not be confused with the means for attaining those goals." The Committee made seven general recommendations intended to rationalize program planning, development, and review; to encourage development and application of uniform and consistent policies and procedures for program planning and implementation; and to improve communication among the NIH staff and among the NIH and other Government agencies as well as the scientific community. Rather than change existing mechanisms or their application, the Committee suggested the development of a rational means for making plans and setting priorities for the application of the mechanisms. These reports focused little attention on the aspects of contract administration and other technical aspects of the contract process, such as cost analysis, statements of work, contract monitoring, and competition. Such attention came later by various investigative/review offices.

Recent Audit Report

During the past 3 years, NCI has been the subject of several reports on contracting activity. These reports dealt with the more technical aspects of contracting; several were

unfairly critical of NCI operations. In some cases, qualifications of the auditors were questioned, as were the methodology and sampling procedures used and the consensus reached. The NIH Director, in a memorandum of October 1978 to the Assistant Secretary for Health, stated: ". . . . (these reports) contain hypotheses and reviewer opinions that have not been subjected to normal post audit dialogue between reviewer and the organization under review. This fact finding and analysis step is critical to establish the validity and reliability of the reviewers' findings and recommendations. It is evident that an auditor or reviewer not required to discuss and explain the basis for his or her findings is given the role of judge, jury and executioner. Unfortunately, this has been the principal mode of operation of the DHEW review teams operating at NIH in recent months." In other cases, NCI and NIH staff agreed with the findings and as a result, were able to make improvements in the contracting activity.

May 1978 Report by the Inspector General, DHEW

The most comprehensive and critical review of the NCI contract program was the May 1978 Inspector General's (IG) Report.

The NCI staff disagreed with many aspects of the report but decided not to respond formally to the draft because they and the IG's staff were to discuss it at a later date. Indeed, in a November 1978 memorandum, the IG noted that efforts to resolve differences in presentation were under way; both staffs met in 1979. In an April 1979 memo, the Chief, RCB, NCI, stated the purpose of the meeting ". . . was to give institute impressions of the report and to identify errors. It was agreed that no purpose would be served by reanalyzing the data to resolve factual discrepancies." Moreover, the IG did not wish to review the report item by item for the following reasons: 1) the IG auditors were not procurement experts and thus could not respond to or perhaps understand NCI's philosophic points, and 2) the IG's return visit would be designed only to cover recommendations made in the report and would not be another audit. Thus errors made in the report were never corrected and differences in opinion never resolved. The NCI's failure to respond to the report led many in the department and in the scientific community to form inaccurate opinions of the manner in which NCI does business. The NCI staff later regretted that it had not rebutted the report more vigorously. In a memorandum to the Assistant Secretary for Health, dated November 1978, the NIH Director stated: "Because there are substantial areas of disagreement in portions of the Inspector General's Report, we regret our earlier decision to not discuss the report in detail on the merits of various issues. Our failure to discuss the draft report when it was issued early in 1978 may have contributed to a misleading impression about the department that we concur in the validity of the IG Report without qualification, which we do not."

June 1980 Report by the General Accounting Office on the Contract Program

This review was conducted by GAO at the request of Congressman David Obey. The request identified several issues in which the Congressman was interested.

This is the most recent examination of the NCI contract program. The report, which involved almost 6 months of field work and several months of drafting, was answered by the NCI, and a copy of the response was included in the GAO publication. However, because of the time constraints imposed by Representative Obey, GAO gave the Institute approximately 72 hours to review the draft and to prepare its response. Then GAO reviewed a total of 5 DCCR (now part of DRCCA) contracts. Several GAO conclusions were based on 3 specific contracts which represented 0.9% of DCCR's contracts. In many instances, NCI found that the GAO conclusions did not give due consideration to the documentation provided. For example, GAO stated that DCCR's contract review groups identified 52 problems and made 43 recommendations. The auditors could find no indication that NCI directed the contractors to implement the review recommendations. The GAO was provided with memoranda from the NCI project officers detailing the corrective and follow-up actions taken by the Institute. Although NCI's documentation could have been better, the Institute had taken adequate steps to correct the problems.

1980 Follow-up Report by the Inspector General of the Department of Health and Human Services

During 1980, the IG returned to NCI to determine how NCI had responded to recommendations made in the May 1978 Report. The final sections of the IG's draft report were received by NCI in mid-November 1980. The NIH response was forwarded to PHS on November 26, 1980. The IG's report showed that NCI had taken many corrective actions, but that further improvements were needed.

Suggestions for Improvement

The following is a brief synopsis of specific suggestions made in the 1978 IG and the 1980 GAO Reports discussed above and the corrective actions taken as a result.

Preaward Process

The reports suggested that 1) comments made about specific contracts by peer or technical review groups were not used by the project officer and contracting officer in later negotiations, and 2) weaknesses noted in the peer review process were not always corrected before the Institute made a contract award. Actually, this is more a problem of inadequate documentation by NCI of its actions than it is of failure to take the actions. The suggestions did result in improvement in documentation of NCI follow-up actions on specific suggestions. The reports also noted a lack of adequate cost analysis of contracts and suggested that statements of work were too broad and the requirements contained in them were poorly defined. The cost analysis problems are real, due to inadequate numbers of contract staff at NIH and lack of lead time in processing contracts. To correct these problems, NCI is working through better education of contract specialists and improved procurement planning to allow more time for cost analysis. Comments about work statements were inappropriate to a great degree, primarily because auditors did not understand that in a research and development environ-

ment, the RFP is deliberately broad to allow for innovative and unique approaches to a problem.

Peer Review

The outside audit reports suggested that occasionally review committees did not reach a consensus because some committee members were absent from meetings and that reviewers were not adequately prepared. This is a rare occurrence, and executive secretaries are continually urged to strive for effective operation of review committees. The reports also suggested that peer reviewers often criticized the quality of proposed efforts. However, in such an instance, the committees usually voted to continue the project. In addition, review committees sometimes take issue with concepts already approved by a BSC, which suggests a need to reinforce the roles of various committees in relation to their memberships.

Contract Administration

This is the area of greatest criticism of NCI contracting activity and the one in which NCI has taken the most corrective actions. The reports made a number of suggestions and comments: 1) Contracting officers and project officers should work more closely together, 2) contract monitoring should be more formal and effective, 3) contractors should provide better reports on the amount of time spent on a contract by their personnel, 4) project officers did not always review progress reports, 5) project officers sometimes provided oral approval to contractors without the contracting officer's knowledge, 6) contracting officers sometimes did not take action after learning that reports had been received, and 7) project officers sometimes did not follow-up on their site visit recommendations to contractors.

To correct these deficiencies, NCI has taken a number of actions. Training for both project officers and contract specialists has been increased. Before 1978, little emphasis was placed on formal training of project officers, whereas now all must receive training. Fifty-seven percent of the project officers have completed the required training. Project officers, contract officers, and principal investigators have been issued a manual on contract administration and a guide for use by principal investigators awarded NCI contracts to help them with their administrative duties. Project officers are required now to review their programs semiannually and to advise their supervisors and the contracting officer of progress and problems. Finally, the number of contract specialists certified pursuant to DHHS guidelines has risen to 50% of those employed and by next year will reach 75%.

General Comments

Three main general comments were made in the reports: 1) The NCI should increase the percentage of awards made competitively; 2) project officers sometimes exert undue influence over contracting officers; and 3) the percentage of obligations incurred in the fourth quarter of the year is too large. As to the number of competitive awards, NCI believes it has a good record. It is estimated that about 60% of NCI contract dollars were awarded competitively in FY 1980. Imprecise and contradictory definitions from DHHS have led to differences in interpreting the NCI record; e.g., NCI does not agree that project officers unduly influence contracting officers. However, the NCI Director has reinforced the contracting officer's independence in the contracting process. As to fourth-quarter obligations, the implication that contracts issued late in the fiscal year are suspect is unfortunate and inaccurate. All contracts take 9 to 12 months of preliminary work before they can be finalized. In FY 1980, NCI obligated 22% of its contract budget in the last quarter; this percentage is not excessive.

Peer Review of Contract Proposals at the National Cancer Institute: Information for Contract Proposal Reviewers

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

CONTENTS

Foreword

As part of its effort to improve its research contracting activities, the National Cancer Institute (NCI) separated the responsibility for the peer review of research contract proposals from program responsibilities in 1978. A Contracts Review Branch was established on August 10, 1979, to be responsible for implementation of these reviews. In March 1981, a decision was made to transfer the review of all contracts to the new Division of Extramural Activities to include the large group of resource and support contracts. The Division is charged with the duty of ensuring that the policies and procedures used provide for scientifically rigorous, fair, and thorough review in compliance with all applicable Federal, Departmental, and National Cancer Institute laws, regulations, and policies. We hope the above changes will provide a necessary consistency in the peer review of contracts across NCI that has heretofore been absent. Although cognizant of the need to conform to all the laws and regulations, the Institute staff is keenly aware that the process is only a means to the end of fostering a research program of the highest possible excellence. In pursuit of this goal, the Institute turns to scientific peer reviewers for assistance in evaluating the quality and suitability of the contract proposals.

Staff of the Institute have compiled this booklet to help peer reviewers understand the principles and requirements of peer review of contract proposals and how they differ from those of grant applications. The pamphlet summarizes the contracting process from the origination of the concept for an activity to the award of a contract. If the reviewers appreciate the relationship of peer review to the other elements in the procurement process, they will be able to provide maximally useful evaluations and recommendations while expending less effort.

Peer review serves as the foundation for the tradition of excellence in research at NCI and the National Institutes of Health. On behalf of all the scientists and clinicians involved in the National Cancer Program and the staff of the Institute, may I take this occasion to express deep gratitude and many thanks to the peer reviewers who by their efforts make the tradition a reality.

Vincent T. DeVita, Jr., M.D.
Director
National Cancer Institute
National Cancer Program

Peer Review of Contract Proposals at the National Cancer Institute: Information for Contract Proposal Reviewers[1]

Contracts Review Branch[2]

INTRODUCTION

This document is intended for the use of consultants who have little or no experience with peer review of contract proposals at the National Cancer Institute (NCI), as well as those who have had some exposure. Consultants who have had experience with the system will note changes arising out of the shift in responsibility for peer review of contracts from the operating divisions to the Division of Extramural Activities (DEA). Reviewers who have had experience in the peer review of grant applications will note differences which arise from the fact that peer review of contract proposals is an integral step in a procurement process. Peer review of contracts provides technical merit review and a numerical score for each proposal. It also discloses significant issues (cost as well as technical) which are essential in the subsequent negotiations with potential contractors and the final selection of contractors. The scores assigned differ from grant application priority scores in that the ratings from which the scores are derived represent assessments of how well each proposal will meet requirements based on the scope of work and evaluation criteria specific to the work to be performed. Priority scores represent an appraisal of the scientific merit of an application compared with an ideal application.

The description in this account is deliberately general. Details will be provided by the executive secretary in charge of your review group or site visit team. You are encouraged to contact the executive secretary at any time to obtain clarification about review procedures or additional information related to the contract proposal(s) under review.

The NCI has determined that it can best serve the interests of its various programs by separating the direct responsibility for the review of all contract proposals (research, resource, or support) from those of the project and contracting officers. To ensure timely and efficient operations, the three arms must work cooperatively, each fulfilling its part of the task. 1) The project officer is responsible for developing the scientific content of the program and its component contracts. He develops the work statements and evaluation criteria and works closely with other staff in developing the timetable for each contract effort. 2) The contracting officer is legally accountable for the whole process (selection as well as administration) and the representatives of the contracting office ensure that the entire process is performed according to regulations. 3) The executive secretary is responsible for coordinating the review of proposals assigned to him/her; for the administrative support of his/her committee; for appointing, with the acquiescence of the branch chief, the chairmen of the committees or the ad hoc review groups; for preparing initial slates of nominees for committee membership, after appropriate consultation with others, including program staff; orienting committee members and keeping them informed; and for documenting reviews by preparing minutes of review meetings that accurately reflect the considerations of the reviewers in arriving at their ratings and recommendations.

Law, regulations, and policy dictate that the contracting officer and the peer review group exert strong influences on the contracting process, and that the project officer and contracting officer are equal partners in a procurement. The project officer should be the dominant official in the triad when program issues are concerned. The purpose of contracting is to support and foster programs. The contracting officer and executive secretary must recognize their subsidiary functions in assisting program staff.

THE NATIONAL CANCER INSTITUTE PEER REVIEW SYSTEM FOR CONTRACTS

Contract proposals are reviewed for technical and scientific merit in a manner similar to grant applications but additional administrative and legal requirements for the award of contracts are stipulated by Federal and Department of Health and Human Services (DHHS) procurement regulations. The National Institutes of Health (NIH) requires scientific peer review of contract proposals which provide innovative and original approaches to accomplish tasks described in a Request for Proposal (RFP). These proposals generally include but are not limited to RFP for laboratory and clinical research, clinical and field trials, epidemiology studies, research and development management, national or regional resource facilities, and innovative development or demonstrations of drugs, devices, systems, or methods. The review of all contracts will be under the control of the DEA. This includes all research and resource contracts. All contracts, with the exception of intramural support contracts, will be reviewed by chartered technical review committees consisting of at least 75% non-Government scientists or ad hoc groups, as necessary. Intramural support contracts will be

[1] Previously published in June 1981.

[2] Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health and Human Services, Bethesda, Maryland 20205.

subject to a parallel review procedure except that committee membership will consist of Government employees. A Scientific Review Committee (SRC) chartered by DHHS at the request of NCI or an ad hoc Scientific Review Group (SRG) is responsible for these reviews. (Throughout this chapter, the initials SRC will be used to designate a chartered review committee. The initials SRG will be used to indicate an ad hoc review group.)

The DEA is also responsible for the review of intramural research support contracts but the review bodies employed for this purpose are of necessity different. This type of review is not discussed in this chapter.

Grants and contracts are currently the major mechanisms for funding of extramural research. The use of another funding mechanism, the cooperative agreement, has recently been mandated. Guidelines for implementing this mechanism are being formulated; present indications are that these cooperative agreements will be reviewed as grants. Grants typically support investigator-initiated research projects, program projects and centers, as well as other forms of assistance, such as fellowships, research training programs, and research career development awards. The contract is used for the acquisition of goods, services, studies, and systems or property, for specific requirements, identified and controlled by the NCI. Contract proposals are solicited through RFP, whereas grant applications are not solicited except in special circumstances.

Negotiated Contracts

Federal policy requires that offerors be treated with complete fairness and that the contractor(s) selected be the organization(s) best able to fulfill NCI's requirements, cost, and other factors considered. To maximize competition, the Federal and DHHS procurement regulations provide two types of selection processes: formal advertising or negotiated contracting. In formal advertising procurement, an "Invitation for Bids" is advertised which sets forth exact, detailed specifications and uniform standards that all bidders will clearly understand, so that price is the major, if not the only, selecting factor. On the other hand, in "negotiated" procurement, the RFP allows latitude in methodology and approach for the advantage of the Government. Therefore, the science is paramount and cost is of secondary importance.

In this context, the word "negotiation" refers to that part of the contracting process which occurs after technical merit review. Each offeror whose proposal falls within the competitive range (which is defined as all those acceptable proposals which have the possibility of being awarded after only minor modifications) is informed of those issues in the proposal that need clarification or modification, or both, as identified during the review. Following oral or written discussion with NCI contracting officers and project officers, these offerors respond with their "best and final offers." These offers serve as the basis for the selection of the successful proposal(s), possible additional negotiations, and award of contract(s). By this means, desirable flexibility is provided to what might otherwise be a rigid system unsuited to research and development procurements.

Overview of the Contracting Process

The majority of contract proposals are received in response to a published RFP. Suitable unsolicited contract proposals are accepted. The determination of the suitability of an unsolicited research or development project for a contract is usually made at the highest appropriate program level. Occasionally, review committees are asked to make this determination when staff expertise is not available. The following discussion is limited to the process for solicited new competing proposals. The process has eight steps:

1) An NCI program staff member (usually the individual who will become the project officer) develops a concept for a project through personal initiative, discussion with advisory groups, consultation with others in the program, and/or interactions with members of the scientific community. The relevance, priority, and need for the anticipated project are determined by staff, and every concept is subjected to a series of internal program clearances. Thereafter, the developed concept must be reviewed for scientific merit and the availability of the required technology and other resources. Under current policy, this review is ordinarily done by the appropriate NCI Division's Board of Scientific Counselors (BSC).

The concept review is concerned with the basic purpose, scope, and objectives of the project as they relate to the desirability of engaging in or promoting the project. The technical review differs from this and is conducted by a separate peer review group which is concerned with the review of the means of accomplishing the project. In arriving at its recommendation, each BSC will, as a minimum, consider the following questions: *a*) Is the proposed project consistent with the mission of the Division? *b*) Are the proposed purpose, scope, and objectives of the project scientifically meritorious? *c*) Are the resources planned for the project adequate to accomplish it? *d*) Is the suggested period of performance appropriate? *e*) Are the classifications regarding resource or research contract and competitive or noncompetitive correct? *f*) In view of the Division's overall resources and its competing activities, is the proposed project of sufficient priority to warrant pursuit? *g*) Is a contract or a grant the most appropriate support mechanism for the proposed activity?

2) Once the concept has been approved, the project officer and the contracting officer develop a project plan, which summarizes the purpose and relevance of the project, provides an estimate of cost and duration, defines special requirements, includes the recommendations of the advisory group(s), and establishes a timetable. The project plan provides the basis for subsequent action.

3) The NCI contracting staff, in conjunction with program staff, then prepares an RFP based on information contained in the project plan and the scope of work and evaluation criteria provided by the project officer. The RFP has a threefold purpose: to convey to prospective offerors the NCI's requirements; to solicit a document that can be evaluated and contains the offeror's proposal for fulfilling those requirements; and to specify the criteria by which all the responding proposals will be evaluated.

To be legally acceptable, the RFP must list in order of importance the criteria to be used for evaluation. A weighting scale must be used if the breaks in the continuity of importance of the listed factors are significant. This scale is used to provide an objective assessment of the relative importance of each factor. It is NCI policy to use weighting scales routinely. Only the evaluation criteria set forth in the RFP may be used in the evaluation. The published criteria may not be modified except by a formal amendment to the RFP. A deadline for submission of proposals (usually 45–60 days following the RFP publication date) must also be specified. The availability of an RFP is always advertised in the *Commerce Business Daily* and is published in the *NIH Guide to Grants and Contracts,* if there is a possibility that an academic institution will compete.

Under certain circumstances, if a proposal arrives after the deadline noted in the RFP and it offers a significant cost or technical advantage to the Government, it may be considered. Cost advantages are determined by the contracting officer. The NCI program staff is responsible for recommendations concerning technical advantages. The peer reviewers may be enlisted to assess the possibility of technical advantage in a late proposal. If a late proposal possesses neither type of advantage, it must not be considered further.

4) Responses to the RFP are checked by contracting or program staff, or both, to ensure that they are complete and that all administrative and other requirements are met and are then forwarded to the assigned executive secretary who coordinates the review. Because of the nature of the negotiation process, proposals are rarely declared unresponsive by staff. Unless the case is completely unequivocal, the staff often relies on the peer review to determine nonresponsiveness.

5) The executive secretary mails the proposals and other pertinent information to the reviewers for their assessments. The mailings are timed to allow the reviewers 4 weeks, if possible, but no less than 14 days to read and become knowledgeable about each proposal before the group meets. Each proposal is assigned for detailed consideration to at least 2 reviewers who lead the discussion on those proposals. After thorough consideration, each proposal is scored and designated as acceptable or unacceptable when the reviewers meet. In an ad hoc group, each reviewer must score each factor for every proposal and provide written comments describing the strengths and weaknesses related to the evaluation criteria. In a chartered SRC meeting, the assigned reviewers provide written comments, whereas the other reviewers are strongly encouraged to prepare concise significant comments at the meeting; all members must rate all proposals. The proposals are ranked by the computed total scores. The committee, if chartered, can accept or adjust the ranking. The NIH implementation of the Federal Advisory Committee Act precludes ad hoc review groups from taking this final step.

Ad hoc review groups are not allowed to make consensus recommendations on either grants or contracts. After thorough discussion, each member privately records a recommendation and rating. Scores are subsequently computed by the executive secretary or the contracting officer's representative. The practical effect is that motions are not made and votes are not taken in ad hoc review groups.

6) Meanwhile, proposals are evaluated independently for business considerations by the NCI Research Contracts Branch (RCB). Business evaluations normally center around analysis of the proposed costs, the contractor's financial strength, and management capability. Direct cost information is made available to members of the SRC or SRG who are expected to assess only the correctness and appropriateness of these costs. Indirect costs, overhead rates, fees, and similar costs are the exclusive province of the NCI staff and may not enter into the scientific merit considerations.

7) The executive secretary forwards the minutes containing the scores, ranking, collated supporting narrative of the individual proposals, and the individual rating sheets for the official record to the contracting officer who convenes a group (usually called a "source selection group," which may be composed of the project officer, consultants and/or other staff members) which advises the contracting officer in the establishment of the competitive range. The competitive range includes all those acceptable proposals which, by minor modification, could successfully compete for award. The determination of the competitive range is based on the technical assessment and ratings as judged by the SRC or SRG and the cost analysis. In nearly all research and development contracts, the costs are considered secondary to good science. Each offeror in the competitive range is informed by the contracting officer of those deficiencies, questions, and other considerations identified by the reviewers and others that apply to its proposal. These offerors are then given an opportunity for oral or written discussions before submitting revised proposals representing their "best and final offer." Throughout the entire process, but especially during these negotiations, great care is taken not to give any offeror an unfair advantage over others. The disclosure to any proposer of ideas submitted by another, the so-called "technical transfusion," is also carefully avoided.

8) A "source selection panel," which at NCI is frequently the same group as in 7 above, or may be an augmented group or a different group, then reviews the best and final offers and on the basis of program priority and balance, cost, and the availability of funds, recommends the proposal(s) which they believe will best fulfill the Government's needs. Although NCI procedures require that only Federal employees participate directly in the actual selection, non-Federal personnel can act in an advisory capacity. Frequently, the executive secretary is invited to serve as an information resource at the selection panel meeting. The legal responsibility for a final decision on an award rests with the contracting officer.

Review of Competitive Procurements

Evaluation Criteria

The criteria published in the RFP are the basis for the peer review. Typical review criteria may include consideration of such factors as:

the proposer's understanding of the goals and scope of the work solicited,

the proposed method(s) for assuring the timely and acceptable performance of the required work,

compliance with requirements of the RFP,

competence of the professional and technical personnel,

technical approach,

scientific organization,

facilities, and

other items related to competence and work statement that may be defined by specific requirements.

The reviewers should also always assess the adequacy of the proposed means for protecting against or minimizing potential adverse effects upon humans, animals, or the environment when any of these elements appear in a proposal.

Reviewers' Preliminary Written Comments

Although legal constraints modify the process, the scientific review of contract proposals is similar to that of grant applications. The executive secretary sends the reviewers copies of all the proposals to be reviewed at a meeting of the SRC or SRG. Each member is expected to read the entire set of proposals and to be prepared to participate in the discussion of each. In addition, the executive secretary designates two lead (often called primary and secondary) reviewers for each proposal. The designated reviewers prepare written comments about their assigned proposals and lead the discussion about these proposals during the meeting. The preliminary written comments, modified to reflect the significant considerations to which the majority of reviewers subscribe, form the basis for the official minutes of the meeting which the executive secretary prepares. Therefore, clear, detailed, and complete preliminary comments are essential.

The Scientific Review Meeting

Standing SRC, chartered under the Federal Advisory Committee Act, meet on a schedule determined to be appropriate to the needs of the program(s) which that committee serves. Each meeting must be advertised in the Federal Register at least 45 days in advance of the meeting. The executive secretary and the chairman of the SRC are in charge of the review meeting. The project officer, who is expected to be present, and the contracting officer or specialist, who must be present, are responsible for providing any necessary background information and for answering any questions about the RFP, or explaining contracts policy, respectively. The NCI staff are required to refrain from making judgmental or evaluative comments or taking advocacy positions. Occasionally, consultants are invited to participate in chartered committee meetings to add special competence needed for adequate review. At such times, the consultants participate fully in the discussion but do not rate the proposals nor vote on acceptability.

In certain situations, the NCI must obtain advice when establishment of a chartered committee is impossible or impractical. For example, ad hoc groups (SRG) are convened when the scientific expertise required to review a set of proposals differs substantially from that resident in any of the available chartered committees. In addition, if a proposal is submitted by a member of the chartered committee which would normally review the responses to that RFP, all proposals submitted for that RFP must be reviewed by another competent review group; if no other chartered committee is available, an ad hoc group must be used.

Recommendations and Scores

When the discussion of each proposal has been completed and the strengths and weaknesses have been thoroughly covered, the chairman will request that each adviser rate the proposal on the basis of the published criteria. A separate score sheet is provided for each proposal; an overall score is computed from the signed, individual score sheets. Reviewers should make additional comments and suggestions concerning the action to be taken with respect to the proposal, especially identifying strengths and weaknesses and any other significant technical or cost issues which will be useful in the subsequent negotiations. Space is provided for comments on the score sheet. Such comments should be given to the executive secretary in written form before the meeting ends if they are not included on the score sheet. Preliminary written comments should be modified to reflect any change in the reviewer's opinion resulting from the discussion.

During the review, all proposals must be categorized into one of two classifications:

Acceptable.—The guidelines for acceptability or capability of being made acceptable by meaningful negotiations are as follows: 1) The proposal must address itself to all essential elements of the RFP. 2) The proposal must show that the contractor understands and appears to be capable of meeting all essential requirements of the RFP. 3) The proposal must be reasonably complete so that a virtually new proposal is not required for it to be made acceptable. 4) Marginally or conditionally acceptable proposals must be considered acceptable. Reviewers should identify the conditions which must be met and the information which must be provided to make the proposal fully acceptable.

Unacceptable.—Unacceptable and incapable of being made acceptable by meaningful negotiations means that without major modification or clarification, *no award is possible.* Proposals with little or no scientific merit are unacceptable. The elements of inadequacy or lack of merit must be documented.

Documentation of Review

After the technical review has been completed, the executive secretary prepares concise minutes which contain a summary of the review comments about each proposal, as well as the roster of the review group. The minutes are maintained as a permanent record in the official files. In preparing the minutes, the executive secretary makes every effort to include all aspects of the reviewers' discussion and concerns regarding the strengths, weaknesses, and any other significant factors which are identified for each proposal. Complete, detailed and accurate information is essential. To ensure completeness and accuracy, the chairman checks and approves the minutes of each meeting before they are finalized and

forwarded. When time permits or if there are complex issues involved, the executive secretary may circulate the minutes for comment to all members of the SRC or SRG. The minutes are then modified as necessary before they are forwarded as approved. The information provided is used by the contracting officer in determining the competitive range. Contracting officers or their representatives may not request the guidance of the technical review group in determining the competitive range. All recommendations of the technical review group must be resolved by the contracting officer or the project officer before any award can be made. The contracting officer also depends on the information in the minutes for the selection of proposals and for debriefing unsuccessful offerors. This assists the offerors to submit better proposals in the future and, if done correctly, reassures them that the evaluation was fair and reasonable. In addition, this document may be used by the project officer in the scientific administration of the ensuing contracts.

Review of Noncompetitive Procurements

Unsolicited Proposals

Occasionally, an organization submits a proposal suggesting a contract-supported project to a specific NCI program that involves work neither requested nor planned by NCI. Program staff then must determine the program relevance, priority and need for the project, and whether the work can only be done by NCI. If all of these conditions are met, if program staff wishes to proceed, and if they certify that the project originated entirely with the offeror without discussion of the details with NCI staff, NCI policy requires that the project be submitted to the cognizant BSC for concept review. Upon approval, a Justification for Acceptance of Unsolicited Proposal (JAUP) is submitted. Approval can be granted by the Chief, RCB, if the budget is below $25,000. Projects having budgets under $100,000 can be approved by the Director of the Division of Contracts and Grants (DCG), NIH. Those having budgets between $100,000 and $500,000 require approval by the Director, NIH, and budgets over $500,000 must be approved by the Assistant Secretary for Health, DHHS. If the JAUP is approved and the proposal is complete, it is forwarded to the Contracts Review Branch. If the contracting officer or project officer requires additional information, a letter requesting it is sent. The response is submitted to the Contracts Review Branch with the proposal for review. This proposal is then reviewed for scientific merit by an appropriate review group. These RFP do not contain evaluation criteria; the factors considered by the reviewers are: 1) the appropriateness of the approach and methodology to accomplish the proposed goals, 2) the qualifications of the personnel, 3) the facilities and resources of the offeror, and 4) the reasonableness of the proposed direct costs. The SRC or SRG then recommends acceptance or nonacceptance of the project; acceptance may be recommended for the total project or for specified parts.

Should the program staff, the BSC, SRC, SRG, or the DCG determine that other organizations have the potential to accomplish the proposed work, the offeror is advised that the award of a sole source contract is not possible. A competitive rather than a sole source procurement may be initiated by program staff, if the offeror agrees. Because a competitive procurement might result in the initiator of an idea losing the contract, program staff often suggest that the originator apply for a grant or seek other means of support before an RFP is considered.

Interagency Agreements

Occasionally another agency, such as the Department of Energy or the Centers for Disease Control, has facilities or expertise which are not available at NCI or a non-Governmental source but are required to accomplish a specific task relevant to or required by NCI programs. In this case, the other agency is requested to submit a proposal to perform the work under an Interagency Agreement. This would be done only after determination of relevance, priority and need by program staff, and concept review by the appropriate BSC. Under NCI policy, such a proposal is reviewed by an appropriate review group using the same factors for review noted under "Unsolicited Proposals."

Renewals

The developmental nature of research contracts often necessitates renewal of a contract to provide for completion of the work statement or for gathering additional data on a continuing basis. Although there is no official NCI policy that stipulates that research contracts be awarded for no more than 5 years at a time, this is usually the time limit for continuation or renewal without a determination on the advisability for recompetition. Sometimes, for reasons such as availability of new technology or the emergence of organizations able to compete, such an activity will be recompeted. However, if program requirements justify continuation of a contract, a Justification for Noncompetitive Procurement is submitted for approval to the Chief, RCB, NCI, or to the DCG, with the same ladder of approval authorities based on cost as noted above in the section on "Unsolicited Proposals." Upon receipt of this approval, a sole source RFP may be issued by the contracting officer requesting a proposal for an additional period. The originally requested scope of work may be slightly modified at this time; however, extensive modifications require a new competitive procurement.

The appropriate SRC or SRG receives the proposal, the proposed work plan, the progress report(s), and the reports of any site visits held during the contract period. The following points are covered in the technical review:

- progress during the previous funding period;
- the scientific merit of the proposed studies in the context of the scope of the work;
- the technical adequacy of the procedures;
- the qualifications, composition, and competence of the staff, as well as the level of effort devoted to the project;
- the availability of special resources, equipment, and facilities if required for successful fulfillment of the contract;
- the proposed period of performance;
- the proposed direct costs;

the protection of rights and welfare of the experimental subjects, if applicable; and

biohazard controls, if applicable.

At the meeting, the 2 lead reviewers begin the discussion based on their written appraisals. Following discussion, motions are made for a recommendation of acceptance of the project as a whole or in part, disapproval, or deferral for further information. If recommended for acceptance, specific recommendations are made regarding the budget and the period of performance. If the group is ad hoc, consensus recommendations are not permitted. After discussion, each reviewer records his individual recommendation. In rare instances, a proposal may contain insufficient information on which to base an evaluation; the SRG can then defer action on the proposal to a future meeting. The contracting officer submits to the offeror the questions formulated by the peer reviewers. The required information is obtained either in writing or at a site visit. The site visit includes one or more members of the SRG and other ad hoc reviewers as required and appropriate NCI staff. The individual site visitors' reports are transmitted to the parent committee or group for action. With an SRG, if it is advantageous, the group may convene on site.

Members also complete ballots with specific written recommendations. These are used by the executive secretary to prepare the minutes of the review meeting that form part of the basis for the contracting officer's decision concerning award of a renewal contract. The minutes and recommendations are also valuable aids to the project officer for the monitoring and scientific administration of the project.

Reviewers should be aware that contracts can be funded for more than 1 year without additional peer review. Often RFP contain scopes of work which require several years to complete. Some contracts under such RFP are renewed on an annual basis following the procedures described above for renewals. However, contracts can be funded in their subsequent years by what is called "incremental funding" or by administrative renewal of the contract each year. The approvals and clearances for RFP for these contracts recognize the intention to provide funding for an extended period that is indicated in the RFP. The contracting officer, project officer, and the executive secretary are all responsible for alerting the peer reviewers when this kind of proposal is being reviewed. In evaluating such proposals, peer reviewers should consider the implications and make recommendations accordingly. The succeeding years of contracts awarded under these circumstances will be funded without further peer review for the number of years approved by the review committee. Policy of the NIH and NCI requires that the contractor's performance always be closely scrutinized by the project and contracting officers. Satisfactory performance must be documented for incrementally funded contracts or renewed contracts before funds for subsequent years are paid. Although NCI policy does not absolutely require it, recompetition of projects which must be extended beyond the fifth year is normally done. New approval of the concept, a new RFP, and subsequent technical review are generally preferred for extensions beyond the fifth year. This is done to ensure that contracts are not continued for prolonged periods without examination of the concept, priority, need, and relevance, as well as a fresh technical review.

REVIEW-RELATED ISSUES

Reviewers' Concerns about Requests for Proposals

In the past, technical reviewers have raised questions about the utility and scientific validity of some RFP; however, this determination is not within the charge of the SRG. The concept of the RFP will always have been approved by a scientifically qualified body, the Division BSC. The publication of the RFP obligates the Institute to consider all proposals seriously. If reviewers wish, they can individually or as a group make known to staff their dissatisfactions with the RFP. Nevertheless, the obligation to evaluate the proposals remains, and reviewers can best assist the Institute by reviewing the proposals to the best of their ability and within the confines of the RFP as published. Program and contracts staff will take note of the reviewers' comments about the RFP and, if possible, use the information during the negotiations for award.

Under extreme conditions, the contracting officer has the authority to reject all proposals or cancel an RFP. However, because preparation of proposals involves expenditure (often significant) of resources by the proposers, arbitrary or apparent thoughtless cancellation of an RFP exposes the Institute to charges of bad faith and may seriously impair important and carefully nurtured relationships between NCI staff and the biomedical community, as well as delay important program activities.

Site Visits

The purpose of a site visit is to allow the team to inspect and evaluate the facility and its resources, including administrative adequacy, and to meet with and evaluate the scientific staff for competence and adequacy to perform the work required. Technical review groups should use site visits only if no other reasonable means exist for obtaining the necessary information. A site visit may be recommended by the review group or a recommendation to site visit may be made by the project officer or by the contracting officer to the executive secretary. Site visits may be made to one or more of the prospective contractors, with fairness the important consideration. If a site visit to one proposer is necessary but would give that proposer an advantage, then any proposing organization which would derive a similar advantage must be site visited. Site visits are rarely justified or necessary for proposals which do not have a reasonable chance for award. Reviewers should consider the costs in time and personnel, as well as money, when recommending site visits.

Site visits are often determined to be necessary by source evaluation or selection panels subsequent to completion of the technical review as part of the remaining selection process. Members of chartered committees are sometimes invited to participate in these site visits as experts. If the member decides to participate, the executive secretary should be informed, and the reviewer should recognize that this activity is independent of the review

committee's function. In such an instance, the reviewer would be serving as a consultant to the project officer or contracting officer, not as a review committee member.

Selection of Reviewers and Standards of Conduct

Selection of Reviewers

Consultants for contract peer review are selected according to the same rules and procedures applying to members of grant Scientific Review Groups. The primary requirement for serving on such a group is demonstrated competence and achievement as an independent investigator in an appropriate scientific or clinical discipline or research specialty. Assessment of such competence is based on the quality of research accomplished, as demonstrated by publications in refereed scientific journals, as well as other significant scientific activities, achievements, and honors. Usually, both a doctoral degree and academic rank of associate professor or equivalents are required, but either or both can be waived for cause. Service requires demonstrated mature judgment, balanced perspective, objectivity, ability to work effectively in a group, commitment to work assignments, personal integrity to assure the confidentiality of applications and discussions, and the avoidance of real, apparent, or potential conflicts of interest.

Recommendations on nominations to membership in NCI chartered scientific and technical review committees are made by the Director, DEA, to the Director, NCI, who makes the actual appointments. Nominees are suggested by executive secretaries following consultation with program staff. Appointments are normally for 4 years and terms are staggered so that about a fourth of the membership of a group is replaced each year. The overlapping appointments ensure continuity. Ad hoc review group members are selected by the executive secretary in consultation with program staff and the Chief, Contracts Review Branch, DEA. Disputes regarding appointments of peer reviewers are resolved by the Division Director involved and the Director, DEA.

Responsibilities of Peer Reviewers

Each peer review committee member should attend as many meetings as possible. Meetings are scheduled as far in advance as practicable. If an absence is unavoidable, the executive secretary should be notified as early as possible. If a cancellation is made after review assignments have been received, the cancelling member should prepare and mail written comments to the executive secretary so that they may be presented at the time of the meeting. If possible, the executive secretary will reassign the proposals to other reviewers.

The following are additional responsibilities of members of the peer review group:

- assessment of each proposal under consideration for its technical and scientific merit in accordance with the published evaluation criteria in the specific RFP; thorough advance study of review materials, including the RFP and the proposals, all site visit reports, if applicable, and supplemental information, if any;
- notification of the executive secretary of any real, apparent or potential conflict of interest;
- service as one of the lead reviewers when so assigned by the executive secretary and preparation of written comments for presentation during the review committee meetings;
- treatment of proposals, review comments, and discussions (written or oral) as privileged and confidential information;
- scoring of each proposal according to specified weights of the evaluation criteria in the RFP; written supportive comments; and return of the signed scoring document to the executive secretary; and
- service as a site visitor when requested, if other duties permit.

Selection and Responsibilities of the Chairman

Selection.—The chairman of a chartered or ad hoc committee is nominated by the executive secretary after appropriate consultation with program staff. The nomination memorandum is submitted to the Director, DEA, through the Chief, Contracts Review Branch, for approval. For chartered committees, a succeeding chairman is appointed approximately 6 months before the current chairman's term ends. Usually this person is already on the committee but this is not mandatory. If the new chairman is to be a person newly appointed to a chartered committee, then that individual must meet all appointment criteria for chartered committee membership. The chairman must be an individual highly respected for scientific accomplishment and have the ability to preside effectively.

Responsibilities.—Although the executive secretary is the Federal person in charge of the meeting, the chairman presides over the meeting and follows the agenda established by the executive secretary.

When the executive secretary has completed the administrative report in the open meeting, the chairman declares the meeting closed, calls upon the assigned reviewers to present their evaluations and recommendations, and then invites additional discussion. During these discussions, the chairman should be fair and firm, encouraging discussion of all positive and negative aspects of the proposal but not permitting rambling or excessively long comments. The chairman should be especially mindful of his responsibility to ensure fair and complete discussion, striving to obtain full expression of all positions on significant questions.

At an appropriate time, the chairman of a chartered committee requests a motion on the proposal. After the motion has been seconded, the chairman asks for any further discussion. When the discussion is concluded, the chairman calls the question and the committee votes on the acceptability or nonacceptability of the proposal. Each member then rates the proposal following the evaluation criteria. If an ad hoc group is working, the motion and the vote will be omitted but the chairman will request each member to rate the proposal on the score sheet. Because the chairman also reviews proposals and votes or rates, this individual may participate in, as well as preside over, discussions.

Meeting minutes.—A major responsibility of the chairman is to review the draft minutes of the meeting after they have been prepared by the executive secretary. The minutes are mailed to the chairman as soon as the executive secretary has finished them. The executive secretary telephones the chairman to obtain his approval or corrections for the minutes at an agreed time. In the review of the minutes, the chairman must ensure that each technical evaluation report contains recommendations that are consistent with the general tenor of the comments made by the committee or SRG members.

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and NIH staff. Members of review groups are requested to leave all review materials with the executive secretary at the conclusion of the site visit or review meeting.

Under no circumstance should reviewers advise potential contractors of recommendations or discuss the review proceedings with them. The review is only one step in the selection process so that reviewers seldom know which proposal(s) will be selected. Premature advice to the proposer(s) may prove embarrassing to all concerned and be a distinct disservice to the proposer(s), who may be led into unwise actions on the basis of erroneous information. Premature notification of recommendations can seriously jeopardize or negate negotiations, may lead to misinterpretation of the discussions of reviewers, represents an unfair intrusion into the privileged nature of the proceedings, and invades the privacy of fellow consultants serving on review groups and site visit teams. Significant effects of such a breach of confidentiality could be the deterrence of qualified consultants from serving on review committees and inhibition of free and full discussion by other reviewers. The protection of the confidentiality of review proceedings is in the best interest of the highly respected NIH peer review system and the NIH tradition of allocating public funds on the basis of research excellence.

Conflict of Interest

Before appointment to a chartered committee and annually during the term of service thereafter, each member completes Form DHHS 474, "Confidential Statement of Employment and Financial Interest." Members of SRC and SRG are considered special Government employees and are expected to comply with normal Federal employee conflict of interest rules during the periods in which they are serving as consultants. The executive secretaries are required to review the Form 474 to be aware of each reviewer's potential conflicts. A peer review group may not review a proposal if one of its members, or his/her spouse, parent, child, or close professional associate is named in the proposal as either the principal investigator or other staff responsible for the program. Instead, review staff must arrange to have such proposals evaluated by some other chartered or ad hoc group.

Reviewers would be considered to have a conflict of interest if they were to participate in the review of proposals from their institutions, even if they have no involvement in the proposal. The reviewer's institution is defined as the entire system, if it is part of a system, rather than the local campus. The state university systems, such as those of New York, California, and Texas, are examples. An employee of the State University of New York, Buffalo, would be considered to be in conflict in reviewing a proposal from an investigator at that university's Albany campus. Whenever peer review group members have participated in the detailed development or review of project approaches of RFP or in post-RFP evaluations, no contracts resulting from that solicitation may be awarded to those members, their relatives, close professional associates, or organizations. Participation in only the presolicitation *concept* review and recommendation does not preclude anyone from submitting contract proposals provided that such reviews and recommendations are limited to the broad purposes and objectives of proposed projects and do not involve the detailed development or review, or both, of a project approach.

At the end of each technical review meeting, the executive secretary obtains written certification from all consultants that the latter have not participated in any reviews of proposals in which they would be in conflict. In competitive procurement, a conflict with a single proposal constitutes a conflict with all responses to that particular RFP.

Reviewers who discover that they have such a conflict should inform the executive secretary as soon as possible and withdraw from the review involved with that particular RFP. With ad hoc reviews, as in all others, the executive secretary will help ensure that no ad hoc reviewers who have a real or apparent conflict are recruited.

To help avoid conflicts of interest and undue influence and to help ensure continuing objectivity in the peer review process, NCI staff may not participate as members of scientific peer review groups in the review of proposals, if they have been or are expected to be involved in decisions or actions in the award or administration of the corresponding contracts. Federal regulations do permit up to 25% of a review group to be *uninvolved* experts who are regularly employed by the Federal government. Project officers and other NCI program and administrative staff are expected to attend meetings of peer review groups assessing proposals within their respective responsibilities, so that they may be aware of the issues and considerations discussed by the reviewers. They also often provide essential technical, administrative, and program information necessary for adequate review and evaluation. Project officers are routinely invited by the executive secretaries to explain the rationale of RFP or renewals. However, they may not join in the scientific or technical evaluations and recommendations of the peer review groups.

Other Considerations

Communication with Offerors

No direct communications related to review should occur between members of the SRC or SRG and offerors. All communications are handled by the executive secretary. Telephone inquiries from offerors to reviewers should be referred to the executive secretary; correspondence from

offerors regarding the review should be sent to the executive secretary, and the offeror should be advised by letter of this action. To ensure the fair and equal treatment of all proposals, only the contracting officer is empowered to contact proposers. Therefore, reviewers requiring additional information should not contact proposers but rather notify the executive secretary as early as possible so that he/she may request it through the contracting officer in a timely fashion for dissemination to all reviewers.

Involvement of Human subjects

According to DHHS policy, the institution that receives awarded funds has primary responsibility for safeguarding the rights and welfare of human subjects who participate in activities conducted under grants and contracts from DHHS. The policy requires that no award may be made until the proposed activity has been reviewed and approved by an Institutional Review Board established by the institution. The offering institution must give the NIH Office for Protection from Research Risks an acceptable assurance of compliance with departmental policy on the protection of human subjects and certify to NIH that the activity has been reviewed and approved before an award can be made. Through its scientific and technical review groups, national advisory boards or councils, and staff, the NIH has the responsibility for evaluation of all applications and proposals for compliance with regulations and policies for safeguarding human subjects. Reviewers are expected to apply the standards commonly accepted in their fields or disciplines. Restricted or conditional awards may be recommended. No award may be made until all concerns or questions have been resolved to the satisfaction of NIH and NCI staff.

The basic DHHS policy for the protection of human research subjects was amended by regulations published in the *Federal Register* on January 26, 1981. In essence, the regulations exempt many classes of research that involve slight or no risk to human subjects and facilitate review of specific types of research that involve only minimal risk. Subjects at minimal risk are defined as those who will be exposed by the proposed research to risks of no greater harm (considering probability and magnitude) "than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests." The new regulations stipulate the composition and responsibilities of Institutional Review Boards and provide them with broad authority and considerable discretion. Applications must fulfill all the requirements of the DHHS policy before they are approved for funding, and reviewers are expected to be familiar with that policy.

Because some time must elapse before implementing rules and memoranda can be issued, reviewers should continue to raise such issues as seem appropriate. Program, contracting, and staff of the Office for Protection from Research Risks will resolve these issues before any contract involved is awarded.

Executive secretaries highlight all special concerns by using a special "Executive Secretary's Note" in the technical evaluation reports. No contracts will be awarded until all concerns about human subjects or those involving animal welfare, hazardous research materials and methods, and recombinant DNA research as described below have been resolved by NCI staff.

Animal Welfare

Proposals for research projects submitted to NIH are expected to comply with the *Guide for the Care and Use of Laboratory Animals* and *Principles for Use of Animals.* Members of all review groups should note any questions or concerns they may have regarding animal welfare. The actual evaluation of the proposals and the ratings are based solely on technical merit; however, reviewers may recommend a restricted award. The Office for Protection from Research Risks has responsibility for Public Health Service policies on vertebrate experimental animals.

The general intent of Public Health Service policy on this point can be summarized in 2 broad rules: 1) The use of vertebrate animals in research should be found to be necessary and justified on the basis of anticipated results for the good of society and the contribution of knowledge, and the work should be planned and performed by qualified scientists; and 2) animals should be confined, restrained, transported, cared for, and used in experimental procedures in such a manner as to avoid any unnecessary discomfort, pain, anxiety, or poor health.

Hazardous Research Materials and Methods

Proposers of experiments involving potential biohazards are encouraged to adopt the advisory guidelines issued by the Division of Research Safety, NIH, for the control of biohazards. These are: *NIH Safety Standards for Research Involving Oncogenic Viruses, NCI Safety Standards for Research Involving Chemical Carcinogens,* and additional standards as they are developed.

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous or potentially hazardous conditions and materials. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the review body in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, and radioactive or explosive materials. If proposed research poses special hazards, these hazards should be identified, and any concerns about the adequacy of safety procedures should be highlighted in written comments for the attention of NCI staff.

Recombinant DNA Research

The Office of Recombinant DNA Activities, National Institute of Allergy and Infectious Diseases, NIH, is responsible for compliance with Federal guidelines for recombinant DNA research set forth in the *Federal Register.* Guidelines have recently been relaxed, but some restrictions still exist. Reviewers are encouraged to express concern regarding potentially hazardous experiments. Any proposal about which concern has been expressed will be brought to the attention of NCI and staff of the Office of Recombinant DNA Activities for resolution.

Lobbying

Members of SRC are required to sign a form stating that they will not engage in any lobbying activities while

employed by the Federal government. All consultants are asked to bear in mind that they are special Government employees on the days they attend review group meetings and should therefore not schedule meetings to discuss their federally funded activities or those of their institutions with NIH staff during those days. The same stricture applies to discussions of specific research requirements with members of the Senate or House of Representatives or their staffs on those days.

Open and Closed Portions of Meetings

A part of all chartered Review Committee meetings (usually the first half hour) is open to the public under the provisions of the Federal Advisory Committee Act. During the open meeting, the executive secretary gives his/her administrative report, and matters of general interest can be discussed. All discussions related to the review of individual grant applications and contract proposals, however, are closed to the public.

Consultant Expenses and Reimbursement

Allowable consultant expenses are round trip air transportation, ground transportation, and per diem allowances which vary according to the location of the reviewer and the meeting. A consultant fee is paid to each participant in an SRG for each day or fraction of a day spent on a site visit or at a meeting of a review group.

Consultants are asked to make their transportation arrangements and to purchase their tickets. Travel should be by the most direct route. Any additional costs resulting from indirect routing or stopovers should be waived or explained if reimbursement is claimed. When air transportation is used, travelers are required to use less than first-class accommodations.

For contract reviews, consultants and members of ad hoc SRG are reimbursed for travel and paid a consultant fee by means of a professional services contract. The executive secretary of the group sends a copy of the group roster to Administrative Services in DEA. A purchase order is prepared with a copy to the reviewer for each reviewer on the roster. The order shows allowable costs which will be paid plus the consultant fee. Invoices are then prepared and forwarded directly to the reviewer. Reviewers are asked to be certain to include their Social Security numbers and home addresses on the invoice to ensure prompt processing and reimbursement. Signing the invoice indicates the reviewer accepts the designated payment as correct. If the reimbursement has been incorrectly calculated, Administrative Services should be contacted as soon as possible, so that adjustments can be made promptly.

Problems associated with the reporting of travel reimbursements and consultation fees to the Internal Revenue Service have occurred. The Internal Revenue Service requires that the travel reimbursements be added to the consultation fees on Form 1099. This results in a report of higher taxable income than is correct, but NCI has not been successful in persuading them to change the requirement. Therefore, reviewers should retain copies of their reimbursement records for income tax purposes. An explanation should be included with the tax return to indicate why only part of the amount entered on Form 1099 is reported as taxable income. This matter is under consideration, and reviewers will be informed should changes occur.

ORGANIZATION OF THE NATIONAL CANCER INSTITUTE

Its Mission

The National Cancer Act of 1971 greatly expanded the responsibilities of the Institute to facilitate the conquest of cancer. The major goal of the NCI is to implement programs designed to reduce cancer incidence, morbidity, and mortality as quickly and effectively as possible.

Organization

Following the most recent reorganization, the research and research-related activities of the NCI are conducted within 5 Divisions, each under the supervision of a Division Director. The functions of the divisions and the major areas of research and research support activities for which each is responsible are described below. Research and resource contracts are utilized by specific programs within all the Divisions except the DEA, as required.

Division of Cancer Biology and Diagnosis

The Division plans and directs the research activities of NCI relating to the biology and diagnosis of cancer, maintains surveillance over developments in its programs, assesses the national need for research in cancer biology and diagnosis, and maintains the necessary scientific management capability to foster and guide an effective research program.

Division of Cancer Cause and Prevention

Areas of responsibility include: planning and directing a program of laboratory, field, and demographic research on the causes and natural history of cancer and on means for preventing cancer; supporting research on mechanisms of cancer induction by viruses and by environmental carcinogenic hazards; and serving as the focal point for the Federal government for the collection and analysis of clinical, epidemiological, and experimental data relating to the etiology of cancer.

Division of Resources, Centers and Community Activities

This Division plans, directs, and coordinates an integrated national program to identify, test, evaluate, demonstrate, communicate, and promote the widespread application of available and new methods for the control of cancer. The staff also plans, directs, coordinates, and evaluates activities in support of cancer centers, research manpower, clinical education, research facilities, and national programs for research in cancer of 4 specific organ sites.

Division of Cancer Treatment

Administrative personnel in this Division plan, direct, and coordinate an integrated program of cancer treatment research activities with the objective of curing or controlling cancer in man by utilizing combinations of treatment modalities, including chemical, surgical, radio-

logical, and immunological techniques; administer a drug development program; and serve as the national focal point for information and data on cancer treatment studies.

Division of Extramural Activities

The DEA provides and coordinates initial scientific merit review of certain grant applications and all research and resource contract proposals submitted to NCI; provides administrative grants management for NCI; processes and issues grant awards; coordinates the implementation of committee management policies within the Institute; and provides staff support for the National Cancer Advisory Board. (Contracts administration is coordinated by the Office of Administrative Management through the Contracts Administration Branch. At present, these activities report to the Office of the Director, NCI.)

The National Cancer Institute Intramural Review Process

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

CONTENTS

Foreword

Science is changing at an ever increasing pace and rapid changes require a willingness on the part of the scientific community to exchange new for old ideas. This is best accomplished through a system of review by scientific peers. We and the community we serve must be assured that we are supporting only the highest quality science in our intramural as well as extramural programs. Because our intramural programs are Government laboratory facilities, they are by necessity operated differently than laboratories and clinics at universities and other institutions. However, there can be no semblance of a double standard for judging the quality of intramural research versus that funded under grants or contracts. To that end, we have developed a rigorous, standardized review process for the science performed in our laboratories that is comparable to the National Institutes of Health grant peer review system. This publication describes the process and should ensure that all National Cancer Institute (NCI) staff members are thoroughly versed on our intramural review process and apply it consistently. Not all institutions understand, or need to understand, the governance of science at other institutions. In the case of the NCI, the close association of the funding of scientific extramural programs to the intramural facilities makes it necessary for our colleagues everywhere to have a clear understanding of how we allocate funds for and review our intramural programs. Toward that end this publication will be made available to the outside community in line with the Institute's continuing commitment to doing business in an open accountable manner.

Vincent T. DeVita, Jr., M.D.
Director
National Cancer Institute

The National Cancer Institute Intramural Review Process[1]

Management Analysis Branch[2]

INTRODUCTION

This document is a staff policy guide designed to ensure a consistent approach to the peer review of intramural research programs throughout the National Cancer Institute (NCI); this chapter also provides information on the intramural review and evaluation processes for those outside the Institute who are interested in or need to know about them. Generally, informational material is presented in the first part of a document. Although each operating division within the NCI uses slightly different procedures for its intramural review process, every division follows the policy guidelines explained here.

THE NATIONAL CANCER INSTITUTE INTRAMURAL REVIEW PROCESS

The NCI conducts intramural cancer research programs in its Bethesda, Maryland, laboratories at the National Institutes of Health (NIH), at other satellite locations in the Washington, D.C. metropolitan area, and at the Frederick Cancer Research Facility (FCRF) in Frederick, Maryland. These programs are operated by 4 NCI Divisions: the Division of Cancer Biology and Diagnosis (DCBD); the Division of Cancer Cause and Prevention (DCCP); the Division of Cancer Treatment (DCT); and the Division of Resources, Centers and Community Activities (DRCCA).

The intramural research programs are qualitatively and quantitatively evaluated in each division by a Board of Scientific Counselors (BSC), a group of non-Government advisers who review the research and make critical peer judgments. Each of the 4 Boards supervises, arranges, and conducts regularly scheduled site visits to each NCI intramural laboratory and branch every 3 to 4 years. Board members review and evaluate not only individual scientific projects but also the overall direction of the intramural research being conducted by the various divisions. Recommendations of the Boards may range from suggested shifts in allocations of financial and personnel resources to changes in program emphasis or even major organizational changes. These recommendations are highly instrumental in shaping the intramural programs of the NCI.

Figure 5.1 depicts the process from the initial determination of a site visit schedule to the follow-up report from the Division to its Board.

[1] Previously published in 1982.

[2] Office of the Director, National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health and Human Services, Bethesda, Maryland 20205.

[3] The RFA is a technique used to stimulate or discern investigator interest in certain scientific areas.

Board of Scientific Counselors

In describing the evaluation of the quality of research being conducted by the NCI intramural programs, one must appreciate the central and pivotal role that the BSC play in the entire process. The NCI is unique among the NIH Insititutes in having multiple BSC (one for each operating division). These Boards are constituted to reflect the mission and composition of the respective programs of each division and have between 15 and 20 members. The law requires that the chairman and at least 75% of the Board members be non-Federal employees. In practice, virtually all Board members are drawn from outside the Government, particularly from academic and other nonprofit institutions engaged in biomedical research. Appointees to the BSC are carefully selected in accordance with Departmental policy to ensure that members have the highest scientific qualifications and that each Board has an appropriate balance of expertise and institutional, geographic, and minority representation. Appointments to the Boards range from 2 to 4 years, and terms are staggered, so that one-fourth of the membership of a group is replaced each year. This staggered rotation not only assures continuity of the Boards from 1 year to the next, but also permits representation of varying points of view.

Responsibilities of the Boards of Scientific Counselors

Each BSC serves several functions within the NCI:

- conducts an annual review of the entire divisional budget at the beginning of each fiscal year;
- approves the concept of each new contract and contract recompetition proposed by the division for the fiscal year, as well as monies to be spent for grants which utilize the Request for Application (RFA)[3] funding mechanism;
- provides advice on all problems that have arisen which would have an impact on the spending plans of the division;
- provides advice on unusual management issues that confront each division; and
- provides peer review of the intramural programs through a process of site visiting (a responsibility addressed in detail in this document).

Role of the Boards of Scientific Counselors in the Evaluation of Intramural Research Programs

The Directors of DCBD, DCCP, DCT, and DRCCA rely heavily on the advice of their respective BSC in evaluating the effectiveness and quality of their intramural research programs. This is particularly appropriate because

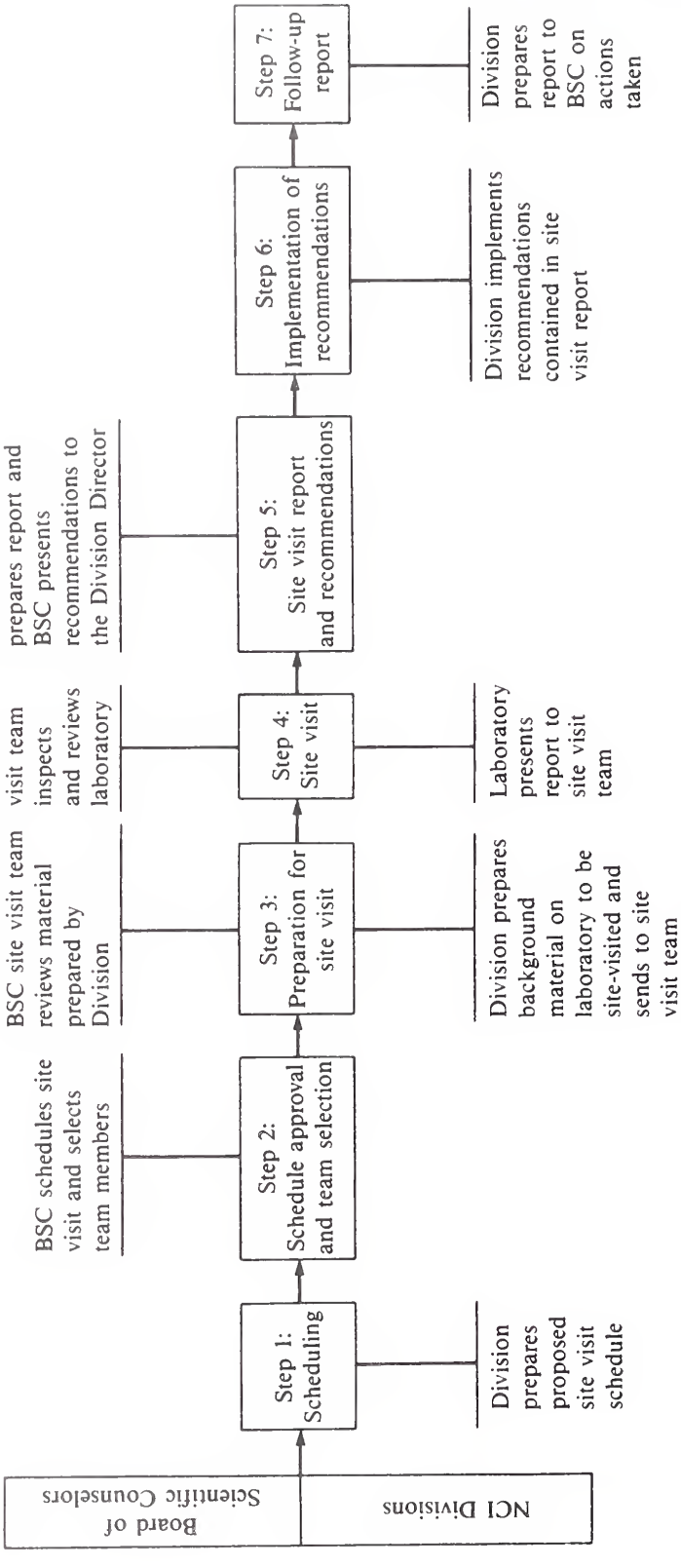

FIGURE 5.1.—Review process of the NCI intramural programs.

each Board also has an overview of its division's extramural programs. Thus they are in a position to judge the balance of resources between intramural and extramural programs.

The Boards are concerned not only with individual research projects conducted by each laboratory, branch, and section but also with the overall scientific direction of the programs being conducted by each division. Division Directors depend on their Boards' advice when making key decisions on such important issues as major reallocations of personnel or financial support, establishment or abolishment of new organizational units or program activities, significant expansion or curtailment of existing activities, and a wide array of other issues dealing with the quality and efficacy of divisional programs. For example: 1) A BSC recommendation was highly instrumental in the decision to establish the Biological Response Modifiers Program within DCT. 2) The DCCP Board conducted, with some assistance from ad hoc consultants, a cost accounting study on an isolated aspect of the Field Studies and Statistics Program to determine if certain patient follow-up studies were being conducted in a cost-effective manner.

Preparation for the Site Visit

Schedule of Intramural Program Reviews

The intramural research evaluation process begins with a schedule of site visit reviews for each of the laboratories and branches to be evaluated by a BSC. This schedule is determined jointly by the Director of each division and the chairman of the BSC in consultation with Board members. The Boards consult with divisional officials primarily on matters such as the timing of the visit. Otherwise, the Boards themselves virtually control the entire process. The review process is continuous. The NCI has 41 intramural laboratories/branches and requires an in-depth review of every unit during each 3- to 4-year cycle. When the schedule is completed, the entire process is begun again. This is consistent with the usual period in which a grant application is renewed and re-evaluated through the Study Section Peer Review System. Such a time frame allows staff to implement recommendations made by the Board during the previous site visit and time for sufficient scientific progress to be accomplished before another evaluation by the Board.

Selection of the Site Visit Team

Once a schedule has been determined and an approximate date for the site visit has been selected, the chairman of the BSC then selects a member of the Board to serve as chairman of the site visit and usually several other Board members, with particularly relevant scientific background, to serve on the team. The chairman of the site visit team chooses ad hoc consultants with highly specialized research expertise when they are needed on a case basis and when that expertise is not available from the Board's membership. This approach expands the research experience base of the Board and ensures a multidisciplinary team that is fully capable of reviewing in detail all the science to be evaluated. Although the Division Director and a few other key divisional staff members are sometimes consulted for their opinions on the need for ad hoc expertise on the site visit team, the chairman of the team exercises absolute authority in the final selection of ad hoc advisers for the visit.

Intramural Site Visit

Usually, site visits require from 1½ to 3 days for the evaluation, depending on the complexity and size of the laboratory/branch and the science to be reviewed. Typically, an evening session precedes the first business day of the site visit, allowing the visitors to convene as a group to discuss their first overall impressions of the background material and, as a group, to clarify areas of concern and questions regarding science or resources, or both. The Division Director and the Associate Division Director, whose program falls within the purview of the site visit, participate in this session.

The first day of the site visit usually begins with a formal orientation by the Division Director and the relevant Program Associate Director and Laboratory/Branch Chief. They attempt to familiarize the site visitors with the relative size and complexity of the laboratory/branch in comparison with others in the Division and to describe its mission within the context of the overall mission of the Division. After this general orientation, the senior investigators of the laboratory/branch give oral presentations to the site visit team on the highlights of their individual research projects. In many instances, reviewers also interview each senior investigator privately, at the reviewer's option, to gain an in-depth perspective of certain projects.

Site Visit Report

At the end of the site visit presentations, the visitors again convene as a group in executive session to discuss and critique the science, and, based on that, the allocation of resources. The Division Director is present at this executive session and participates in the discussions. A consolidated report is prepared by the site visit team and is sent to the Division Director and each Board member at least 1 month before the next meeting of the Board. The site visit report is discussed and modified at the next full meeting of the Board in closed session and then declared by majority vote to be the Board's recommendations for consideration by the Division Director.

IMPORTANT POLICY REQUIREMENTS IN THE INTRAMURAL REVIEW PROCESS

A consistent approach to the peer review of intramural research programs throughout NCI is assured by certain aspects of the process that have been established as standardized requirements throughout the Institute. These requirements are discussed below.

Specific Intramural Issues Addressed by the Boards of Scientific Counselors

When conducting reviews of intramural programs, each Board is asked to:

determine the relevance of the science of the NCI laboratories/branches to the mission of the division;

determine the necessity or desirability, or both, of ongoing intramural efforts in specific areas conducted by the NCI laboratories/branches;

assess whether the quality of science is sufficient to warrant the current level of resource support of the organizational units, projects, and senior investigators devoted to these areas; and

identify additional areas of science that should be addressed by NCI intramural laboratories/branches or programs based on evolving state-of-the-art developments in cancer research as a whole.

Advance Preparation by the Site Visitors

At least 1 month before the site visit is to take place, the laboratory/branch submits a package of background review materials for the reviewers to read before the actual scientific presentations are made during the site visit. This written material is similar to that provided by a grant applicant of a program project (P01) and describes the past accomplishments of the laboratory/branch, its current activities, and its future plans. Not only science but also resources including space, personnel, and funding are discussed. These packages include: 1) a description of the division's organization and functions by laboratory/branch and section; 2) information describing current and future research activities by section and project; a list of all personnel including curriculum vitae of all professional employees; a detailed compilation of resources for each laboratory/branch (broken down to the section level when applicable), which includes 1) space data, i.e., square footage, type of space, and floor plans; 2) personnel resources, e.g., the number and types of personnel in a given laboratory; and 3) operating costs, expenditures by major direct cost category, such as personnel, supplies, equipment, travel, etc., and information on indirect cost.

Although the organization of and format for this material may vary slightly from division to division, each organization must provide the same base-line information to allow the members of the Boards and the site visit teams to compare one component with another, as well as to correlate this information with that derived from their experience in reviewing grant and contract applications.

Composition of the Site Visit Report

Although the style and format of the site visit reports may vary slightly because of the preferences of each Board, every report will have these common components: 1) a descriptive narrative that includes *a*) a review of past, current, and proposed future research activities; *b*) a critique of each research project and senior investigator; *c*) a critical assessment of the resources allocated to the organization and projects under review; 2) a qualitative judgment on the merits of each research project; 3) observations on the relevance and direction of the research under review in relation to the mission of the laboratory/branch, its parent division, and current cancer research developments outside the NCI; and 4) a summary of the Board's major comments and observations to include distinct, specific recommendations for action by the Division Director that flow from the Board's judgmental evaluation of the items cited immediately above. These recommendations obviously will vary from one laboratory/branch to another. Typically, they encompass such aspects as redirection, intensification, or de-emphasis as appropriate for specifically identified segments of the research efforts that were reviewed; reallocations of resources; or, possibly, reorganization steps that might foster better collaboration between certain investigators whose research efforts are becoming closely related.

Follow-up on Recommendations of the Boards of Scientific Counselors

After the site visit report is adopted by the Board, it is forwarded to the Division Director for consideration and implementation of the recommendations. The Division Director will meet with the appropriate Program Associate Director to discuss the site visit report and the recommendations it contains. The Associate Director then meets with the responsible Laboratory/Branch Chief for continued discussion and planning of implementation actions. The Chief of the Laboratory/Branch ordinarily has the primary responsibility to see that any changes in research are operationally implemented, with the actual implementation usually done through the respective section chief(s). The Division Director and the Associate Director for the program involved are ultimately responsible to ensure that the changes are made. This responsibility flows through the typical chain-of-command pattern that is common to the intramural programs of all divisions. Resource reallocations involve the Laboratory/Branch Chief, but most major action steps must be taken at higher levels to coincide with the Institute's resource management process.

Division Report to the Board of Scientific Counselors on Implementation of Site Visit Recommendations

Approximately 1 year after receipt of the site visit report, a follow-up report is presented by the Associate Program Director or Division Director to the Board. This report demonstrates how the division has responded to the Board's criticisms and recommendations. It specifies 1) the recommendations that were accepted and the steps taken to implement them; 2) any remaining implementation actions and a proposed time frame for accomplishing them, and 3) any recommendations with which the division may have disagreed or considered impractical and the reasons for such disagreement.

When the Board recommends substantial changes in the operations or organization, or both, of certain intramural laboratories/branches, it is not always possible to implement the recommendations meaningfully within 1 year. In such a case, the division will make a second follow-up report to the Board, usually within 18 months after the initial discussion of the site visit report.

Three to 4 years later, the entire process begins again for the same laboratory/branch, and the previous site visit results are incorporated as one of the considerations in that next review. Also, some of the reviewers from the previous site team will be used again for continuity. If necessary, former Board members whose terms have expired will be used as ad hoc reviewers on the subsequent site visit.

APPENDICES

A: Report on NCI Management Efforts and the Impact on Research

B: Guide to the Principal Investigator of NCI Contracts

C: NCI Manual for Contract Administration

Report on NCI Management Efforts and the Impact on Research

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Cancer Institute

REPORT ON NCI MANAGEMENT EFFORTS AND THE IMPACT ON RESEARCH

Thomas E. Malone, Ph.D.
Deputy Director, NIH

March 1983

CONTENTS

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D C 20201

The Honorable Lowell P. Weicker, Jr.
Chairman
Subcommittee on Labor, Health
and Human Services, Education
and Related Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I am pleased to transmit herewith a report requested in the Senate Appropriations Committee Report No. 97-680 accompanying H.R. 7205, the FY 1983 Appropriations Bill.

The report is on: NCI Management Efforts and the Impact on Research.

Sincerely,

Dale W. Sopper
Assistant Secretary for
Management and Budget

Enclosure

cc: The Honorable Mark O. Hatfield
Chairman, Senate Appropriations Committee

Appendix A: Report on NCI Management Efforts and the Impact on Research [1, 2]

National Cancer Institute [3]

EXECUTIVE SUMMARY

In Senate Report No. 97-680, the Committee on Appropriations noted current budgetary restraints and requested that the National Institutes of Health prepare and submit a report on the progress and effectiveness of management initiatives, including reallocation of resources, taken by the NCI to maintain an effective level of support for advances in the vanguard of biological research. The following is submitted in response to that request.

Background

The two major approaches taken by the National Cancer Institute (NCI) to enable funding of critical new research activities are: 1) thorough and judicious management of expenditures of existing resources and 2) specific decisions to reallocate resources based on scientific priority. The Institute utilizes a corporate model of decision making exercised through an Executive Committee composed of all five division directors, the Institute Director, Deputy Director, Associate Director and Executive Officer to determine all major scientific and operational policy. The National Cancer Advisory Board and the divisional Boards of Scientific Counselors provide expert advice on matters of science, priorities and resource allocation.

Accomplishments

The resources utilized by the Institute in pursuing research in cancer treatment, biology and diagnosis, etiology, prevention and control can be classed as money, people, space and equipment. Supplies of all of these resources are constrained and a premium has been placed on managing them tightly and making the hard decisions about their best investment for maximum research return.

Since 1980, every existing NCI contract has been reviewed and research and development contracting reduced by $40 million, as has been discussed with the appropriations committees during last year's hearing. These funds have been expended largely for research grants in scientific fields related to the previous contract research. To maximize the use of existing resources, a number of grant funding policies have been adopted to stretch grant dollars and permit funding of a larger number of approved research project applications. Program management, business management, and review of grants and contracts are now in separate organizational components to maintain integrity and rigorously perform each function. Grant and contract business management have been consolidated in the Office of Administrative Management. All review of applications and technical review of contract proposals not performed by the National Institutes of Health (NIH) centrally are carried out by the Division of Extramural Activities, NCI. A number of additional measures taken to monitor grants and contracts are outlined in the report.

NCI senior management has reviewed all positions and space assignments in the past year and property inventories are being updated. In areas where staffing has been judged not to be consonant with productivity and scientific or program priority, positions have been reassigned to provide additional personnel for new programs in such areas as applied prevention research, radiation research and intramural research on monoclonal antibodies, biologic response modifiers, and oncogenes. Space moves have been initiated to co-locate staff working for a particular program or office.

To preserve the principle of parity with the research project grant pool, intramural research has been held to a four percent increase in FY 1982 and FY 1983. NCI laboratories have had to operate within similar fiscal constraints as those experienced by extramural grantees. The science in intramural laboratories is periodically reviewed by site visit teams under the direction of the divisional Boards of Scientific Counselors in a system analogous to reviews of grant applicants. Through redirection of space, scientists and dollars, laboratories are formed or reconstituted to pursue the most promising avenues of investigation, which in the past two years have included research on monoclonal antibodies/hybridomas, oncogenes, retroviruses, biological response modifiers, and carcinogenesis.

Knowledge gained from basic research and epidemiologic studies is providing the foundation for major new applied research programs in cancer control and prevention. Organizational and planning foundations have been laid over the past year and grantees will begin to be funded during FY 1983.

Conclusions

Despite budgetary constraints, the NCI, through continued management improvements and careful reallocation

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[1] Previously published in March 1983.

[2] Inasmuch as this report was submitted to the Congress, it has not been edited to conform to the style of the *Journal of the National Cancer Institute* Monographs as other chapters were.

[3] Prepared by the National Cancer Institute at the request of the Senate Committee on Appropriations, 1983.

of resources to high priority activities, intends to continue to support fundamental research in the forefront of biological science and to apply the fruits of this research to controlling and preventing cancer.

INTRODUCTION

In its report on the Fiscal Year 1983 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

"The Committee notes recent efforts at NCI to assure continued support for the most worthy research despite budgetary constraints. This support is especially critical in view of the revolutionary strides taking place in fundamental biology today. In order to maintain an effective level of support for this research, NCI has adopted several streamlining measures, including a reallocation of resources, where appropriate. The Committee hopes these measures will be effective and requests that NCI provide it with periodic management reports on the progress of its efforts and the impact on research." (Senate Report No. 97-680, page 34.)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

In order to support new programs and research endeavors in the light of resource constraints, NCI has followed two basic principles. These are: (1) rigorous management of those resources made available by Congress, and (2) redirecting support from lower priority to higher priority areas. The former requires careful attention and review by top management to the way resources are allocated and controlled. The latter entails difficult decisions regarding which activities should have their support reduced or withdrawn. These resource allocation decisions rest on informed scientific assessment of the relative merits of a number of possible research initiatives, all of which are worthwhile.

The National Cancer Institute has adopted a corporate model of decision making to address major issues of management, resource allocation, and priority setting. The NCI Executive Committee has been reconstituted to include the Director, Deputy Director, Associate Director, Associate Director for Administrative Management, and the five Division Directors, heightening the weight of representation from the division in relation to that of the Office of the Director. At its weekly meetings, the members jointly consider all key operating and policy decisions affecting the Institute. At two Director's meetings in February and July, the Executive Committee makes cross Divisional allocation decisions in planning for budget planning and operations.

Further review and guidance are provided by the President's Cancer Panel, the National Cancer Advisory Board (NCAB), and the four divisional Boards of Scientific Counselors (BSC).

ACCOMPLISHMENTS

The resources of the Institute can generally be classified as people, dollars, space and equipment. To be able to support quality research in the forefront of science in the intramural as well as the extramural program, the Institute must manage all of its resources for maximum return. This includes reducing support for some areas and redirecting it to others.

General Reviews

As a basis for resource allocation decisions, existing distribution and utilization of resources have been thoroughly reviewed so that they could be adjusted to ensure consonance with program and scientific imperatives.

Each year, at the February Director's Meeting, the Executive Committee establishes budget policy for the next fiscal year which can include redistribution of budget allotments across Divisional lines. Operating plans for the current fiscal year are also reviewed. At a July Director's Meeting, specific Division levels are established for the coming fiscal year. A number of additional NCI budget planning steps are outlined in the attached timetable.

During FY 1982 position reviews were conducted by the Director for all organizational components of the Institute in which staffing was evaluated against the overall needs of the Institute and excess resources identified. Case by case review by the Director, NCI has been required to recruit for new staff, even when replacing those who resign. This has allowed the shifting of position allowances to programs and offices judged to require augmented staff, be it to improve management, initiate a program or expand specific research efforts.

A total review of space assignments was also held during FY 1982. The objectives were to reduce space for activities being deemphasized, identify space for new programs, colocate staff of each program or office and to return laboratories from leased contractor space to the Bethesda campus or to the Frederick Cancer Research Facility (FCRF). This fosters communications between intramural investigators and moving from leased space to the FCRF results in cost savings.

An Institute-wide equipment inventory is nearing completion and will provide accurate and up-to-date information regarding furnishings and research equipment. Return of equipment from contractors, upon completion of a contract, for use at NIH is being re-emphasized.

Programmatic Reviews

Dollars spent for grants and contracts and for intramural research are continuously reviewed to assure that public funds are expended for maximum scientific return in support of the objectives of the National Cancer Program.

These reviews have stressed evaluation of return for resources invested and have resulted in redistribution of resources to activities expected to be more productive or of greater scientific importance. We cannot afford to review for a purely abstract level of quality, but must also assess for the likelihood of producing knowledge which will be of greatest use in determining the causes, cures and control of cancer.

Some of the changes resulting from these reviews include:

Consolidation of all radiation research activities into the Radiation Research Program in the Division of Cancer

Treatment (DCT) with concomitant transfer of the Diagnostic Radiology Section from the Diagnosis Branch, Division of Cancer Biology and Diagnosis (DCBD).

Orderly transition of the Baltimore Cancer Research Program from an NCI operated program to a grant supported Cancer Research Center. Costs went from $7,858,000 in 1980 to $1,993,283 for FY 1983.

The DCBD abolished the Laboratory of Immunodiagnosis and the Laboratory of Theoretical Biology. It also established the Laboratory of Mathematical Biology, Laboratory of Tumor Immunology and Biology, Laboratory of Genetics and added a Tumor Invasion and Metastasis Section in the Laboratory of Pathology.

The DCT merged two laboratories in the Developmental Therapeutics Program to reduce overlap. It also effected savings by eliminating the plant collection program. This was possible because large numbers of plants are sent to us for testing at no cost. The savings are being used to establish new centers for drug synthesis and testing and to expand the monitoring of clinical trials.

The Division of Cancer Cause and Prevention (DCCP) established the Laboratories of Human Carcinogenesis, Comparative Carcinogenesis, Molecular Oncology, and Cellular Carcinogenesis to study chemical and biological carcinogenesis.

The greatest changes are taking place in the Division of Resources, Centers and Community Activities (DRCCA) which has undertaken the planning of a major reorganization and new program development. This effort will result in the first time award of grants in the new programs during FY 1983.

On the advice of DRCCA Board of Scientific Counselors, funding was reduced or cut for three programs: (1) the Centralized Cancer Patient Data Systems, (2) Centers Outreach, and (3) Cooperative Groups Outreach. These programs were either service oriented and had a finite life as demonstration projects or were not achieving cancer control research objectives.

Funds are being directed to new programs of research on the prevention and control of cancer. The development of these programs has grown out of a lengthy process of consultation with the NCAB, the DRCCA Board of Scientific Counselors, and researchers and clinicians across the country. A strong commitment to evaluation is being made from the start. Data has been accumulating which now provides an opportunity for human intervention trials in chemoprevention, smoking cessation and prevention, and diet, nutrition and cancer. The new Community Clinical Oncology Programs and Cancer Control Research Units will afford not only an opportunity for the cadre of oncologists trained over the last decade and now practicing in the community to participate in clinical trials and control research, but is expected to have a diffusion effect among other health professionals in the community.

Contracts and Grants

In FY 1981, it was decided to centralize all business management of grants and contracts in the Office of Administrative Management (OAM) to assure uniform implementation of business decisions from one focal point in the Office of the Director, NCI. Responsibility for peer review is now focused in the Division of Extramural Activities (DEA), separating the review of applications from program management. This has entailed the relocation of the Grants Administration Branch and the Grants Financial and Data Analysis Branch from DEA to the OAM. All peer review which had been carried out by program divisions has been relocated to the DEA. Here all those grant applications which are not reviewed by the Division of Research Grants, NIH, are peer reviewed and all research and development contracts receive expert technical merit review. Thus review, program management and business management of grants and contracts are insulated from each other, promoting the integrity and rigor of each activity.

All proposed contract concepts and Requests for Applications (announcements of targeted grant programs to invite applications to pursue research in areas judged to need stimulation) are brought by the respective Division Director to the Executive Committee for review. If approved by the Executive Committee, they are then reviewed by the appropriate Board of Scientific Counselors (external peer review committees) for merit, relevance to the mission of the Division, and level of resources required. Contract concepts for the Office of the Director, NCI, are reviewed by a subcommittee of the National Cancer Advisory Board. All of these reviews are substantive and a significant number of proposed contract concepts and RFAs are altered or disapproved.

As discussed with the Committee during last year's hearing, since the beginning of 1980, every existing NCI contract has been reviewed by the Executive Committee with a resultant identification of $40 million of activities that were reduced or eliminated. These cuts were taken from contract support to the intramural laboratories and by discontinuing the use of the contract mechanism to fund research. Although contracts were needed to promote research in critical areas early in the Cancer Program, there is now sufficient activity to switch to the grant mechanism. A major portion of this $40 million was reallocated to awarding additional investigator initiated research grants.

The single large contract for the operation of the Frederick Cancer Research Facility was recompeted as five separate contracts in FY 1982. This decision was based on the desire to increase competition and a concern that the number of potential bidders for the large contract was limited. Each contract was awarded to a different proposer, four of which were small businesses. The magnitude of this effort required complex planning and tight timetables to assure that all awards were made ahead of schedule, and that no extension of the existing contract was required. The dollar amount of the contract for contractor-initiated research was reduced by 29 percent. A reorganization was implemented that centralized the management of Frederick under an Associate Director, NCI. He established the NCI Frederick Cancer Research Facility Advisory Committee to provide consolidated external peer review of the quality of the contractor initiated research.

The reforms in contract review and management outlined by Dr. DeVita at the Senate Committee on Labor and Human Resources hearing on National Cancer Institute Contracting and Procurement Procedures on June 2, 1981,

have yielded good results. In addition to those changes, all contract officers have received required training, internal reviews have been conducted of all contract administration teams and follow-up reviews will be completed soon. Each division has appointed a senior staff person as Chief of Project Officers. This person assures that all project officers meet current training requirements, are informed of policies related to their duties and comply with reporting and site visiting requirements. An automated contract administration system has greatly improved the timely receipt of semi-annual reports from project officers. Guidelines have been set for site visit requirements to contractors by both program and contract staff. The Office of Procurement, Assistance and Logistics, HHS, the Public Health Service, and the NIH Division of Contracts and Grants have all confirmed that problems in contracting reported in 1981, by the Inspector General, have been corrected.

A pay-back policy was initiated in FY 1981 whereby certain products produced or stored by NCI or under contract are no longer distributed free of charge to users. Grantees, contractors, and NCI intramural laboratories must now pay for the costs of these products. The amount paid is deducted from NCI payments to the contractor producing or distributing them. This change promotes more judicious ordering of the products. Costs for these products are reviewed during the peer review of grants and review of contracts. These expenditures are also considered during site visits to intramural laboratories promoting greater cost consciousness in ordering. Savings to NCI in FY 1982 were close to $1 million.

In the past, with few exceptions, paying the best research project grants at the full funding level recommended by study sections was possible. The large number of approved NCI research project grants relative to available dollars stimulated examination of a number of funding options in order to be able to make a larger number of awards in a time of level budgets. In FY 1982, the NCI adopted a funding plan which called for R01s, or basic research project grants, which were competing renewals to receive an increase of not more than eight percent over the previous year's level even if more had been recommended by the review committee. Non-competing and new grants were cut by four percent from recommended levels. These reductions resulted in our being able to pay to a priority score of 183 compared to 175, which would otherwise have been the case. The Executive Committee, however, retains the option to pay a grant at recommended level on the basis that the science is important and could not be carried out at the reduced level.

P01 or Program Project Grants are typically large grants of close to $1 million involving a number of research projects and support for a coordinating function. The NCI will discontinue allowing review committees to drop disapproved projects from inclusion in the total score. Including them in the computation of the total final score should stimulate grantee institutions to select more carefully the individual projects to be included, reducing overall size and cost and promoting uniform high quality. An ad hoc subcommittee of the National Cancer Advisory Board is studying how the components of a P01 grant should be weighted as they are not all equal in size or importance and make recommendations to the Institute. The new policy is slated for implementation in FY 1984.

The NCI, in consultation with the NCAB, has determined that in FY 1983, R01s and P01s will be cut 15% from recommended levels and all other grant programs will follow this guideline. Divisions retain authority to alter individual grant funding plans by 10% within the allocated budget for each grant activity.

Further economies in grant funds will be achieved by altering previous policy on interim and phaseout funding. NCI had been the only institute which provided phaseout support to grantees who did not have a priority score high enough to win a competing renewal. In FY 1982, the Institute changed this policy to give phaseout support only to grantees whose priority scores were above the pay line for the previous year. In other words, if the competing renewal grant application received a priority score which would have been paid the year before, but the cutoff priority score had changed so that it was no longer eligible for funding in the current year, it would have been eligible for phaseout support. In FY 1983, phaseout support will be provided only for Core, Headquarters, and Training grants. Exceptions to the phaseout policy are dealt with on a case by case basis by the Executive Committee of the Institute. Grantees receiving poor peer review scores will receive early notification from the program director so that they will be able to prepare for discontinuation of NCI funding.

Interim support will be provided when there has been approved delay in submission of a renewal application, review of an application is deferred by NCI or NIH, or program staff wants to provide another opportunity for an investigator to compete for reasons of high program or scientific relevance.

In FY 1983, the savings accrued from these revised interim funding policies will be utilized to fund other grants.

On occasion, a grant application which appears novel and risky, but potentially important scientifically, does not receive a good enough priority score to be funded. Such grants may be funded, however, as exceptions. Likewise, a grant with a score within the pay range may be judged less important to fund. All program recommendations to skip a grant above the payline or pay a grant below the payline are brought to the Executive Committee by the appropriate Division Director. Discretionary decisions to pay grants out of order are made, but only as the result of actions of this body. The NCAB is informed of all such actions.

Formulae for periodic site visiting of grantees by grants management staff have been established to ascertain the adequacy of the business management of federal funds and compliance with other administrative requirements by the grantee institution.

Each program division has appointed a Chief of Program Directors to advise on grants policy and provide guidance to staff responsible for managing extramural grant programs. This group is chaired by the Director, Division of Extramural Activities, and addresses common issues affecting grant programs.

The Grants Administration Branch has established the position of Internal Auditor for the purpose of conducting management reviews of the quality of grants administration as documented in official files, identifying weaknesses and

developing procedures to assure consistent overall quality of grants administration.

An NCI manual issuance established an Institute Alert System policy for handling allegations, formal or informal, of wrongdoing by recipients of NCI grant and contract support as part of the NIH effort to deal with misconduct in science.

Following a study by an ad hoc subcommittee of the National Cancer Advisory Board, a decision was made to restructure the Organ Site Program. This program provides grant support of targeted and coordinated cancer research for cancer of the urinary bladder, large bowel, pancreas and prostate. The four external headquarters will be consolidated into one and review of the individual grants will be conducted by committees convened by the Division of Research Grants rather than by externally organized peer review groups. This change will result in a reduction of administrative costs and insure that the review of research is consistent with that for R01 applicants. The external headquarters will continue to provide coordination and workshops and to stimulate needed research. The Committee, in its report on the 1983 budget, expressed interest in discussing this subject during its deliberations on the 1984 budget.

Intramural Research

The intramural program is being remodeled on an ongoing basis to assure that our intramural research is in the forefront of science and has the highest promise of fruitful results. In FY 1982 and 1983, the intramural program has been held to a four percent increase in the interest of parity with funding levels for the research project pool, so that the intramural laboratories are operating within the same financial constraints as the extramural grantees.

All intramural laboratories are site-visited on a periodic basis by special site visit teams under the direction of the divisional Board of Scientific Counselors. The Board Chair appoints the members of the team which includes other board members and expert consultants with special expertise qualifying them to evaluate a particular laboratory. Prior to the site visit, the team members receive a package of material similar to what would be required of a grant applicant. The site visit includes special presentations and individual interviews with investigators, and addresses scientific accomplishments and directions and the resources allocated to them. The report of the site visit team is presented to the Board of Scientific Counselors which makes recommendations to the Division Director. A year following the site visit, the Director reports back on steps taken to implement the recommendations or the reasons for not doing so. This newly developed process is structured to recur on a rotating basis of about five years and subjects our intramural scientists to a rigorous review at least equivalent to that required of grantees. It has been described in a recent NCI publication for the information of the entire research community. A study of the intramural program, done by the General Accounting Office (GAO) in 1982 at the request of a member of the Senate, found no problems to report and informally noted the rigor of the site visit process.

Utilizing the site visit process and the space and position reviews, resources which can be reallocated have been identified. This has allowed the development of new laboratories and expansion or reorientation of existing laboratories to pursue research in the revolutionary new areas of hybridomas and monoclonal antibodies, oncogenes, retroviruses, and biological response modifiers.

Applied Research

The knowledge gained in the ten years since the passage of the National Cancer Act has laid the foundation for a national program of applied research in cancer control and prevention. Even though progress in cancer treatment has been dramatic, knowledge gained in the laboratory and through epidemiologic studies is sufficient to justify the expenditure of resources for research on the prevention and control of cancer with the reasonable expectation of sound results. The Division of Resources, Centers and Community Activities is the locus for this new thrust. Starting with the recruitment of a Division Director in FY 1982, considerable effort is now going into program planning, organizational development, and recruitment for leadership positions. FY 1983 a number of major new extramural grant and cooperative agreement programs have been developed, reviewed by the Board of Scientific Counselors and subsequently announced.

In FY 1983, applications will be reviewed and awards made for Cancer Control Research Units, Community Clinical Oncology Programs, Cancer Control Clinical Cooperative Groups and a new program in chemoprevention. The latter is a prospective study on the effects of micronutrients on cancer incidence. We expect to report to the Committee toward the end of the fiscal year on the numbers and types of grants awarded and the characteristics of the successful applicants.

CONCLUSIONS

It is the intention of the NCI to continue to manage and reallocate resources carefully and rigorously, to enable us to expend them where we anticipate the most valuable results. This is the only way we will be able to continue to stay on the cutting edge of science and to apply new knowledge to research on the control and prevention of cancer.

Major Steps in the Budget Formulation Review Process

	January	February	March	April	May	June	July	August	September	October	November	December
1 NCI Staff	NCI Director's Mtg. - establish overall budget policy for upcoming fiscal year; review operating plans for current fiscal year Submit Congressional justification for next fiscal year		Formulation of Prelim. Budget for two years in future for both the By-Pass, and budget submitted within the Administration's guidelines Congressional Testimony by Director, NCI			NCI Director's Mtg. - establish specific division levels for upcoming fiscal year		Formulation of By-Pass Budget Formulation of Budget within Administration guidelines		Formulation of President's Budget		
2 NCAB				Review and revise Prelim. Budget for two fiscal years in future					Review By-Pass (OMB) Budget submitted directly to the President		Division presentations of program activities for fiscal year just completed	
3 BSC	Review operating plans for current fiscal year and policies from NCI Director's Mtg.					Review and advise on implementation of specific divisional programs for current fiscal year			Annual Division Budget Reviews current and future plans			

1. Executive Committee and key administrative staff
2. National Cancer Advisory Board—presidential appointees
3. Boards of Scientific Counselors—outside NCI peer review bodies for each of four operating divisions

Guide to the Principal Investigator of NCI Contracts

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

CONTENTS

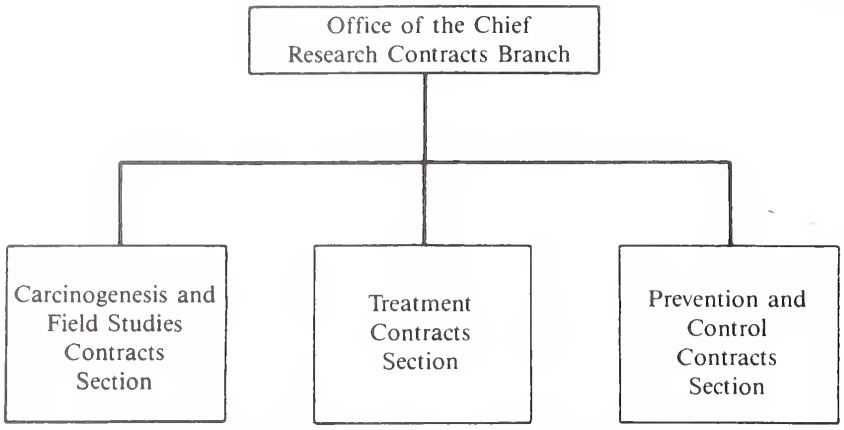

FIGURE 6.1.—Organizational chart of the Research Contracts Branch.

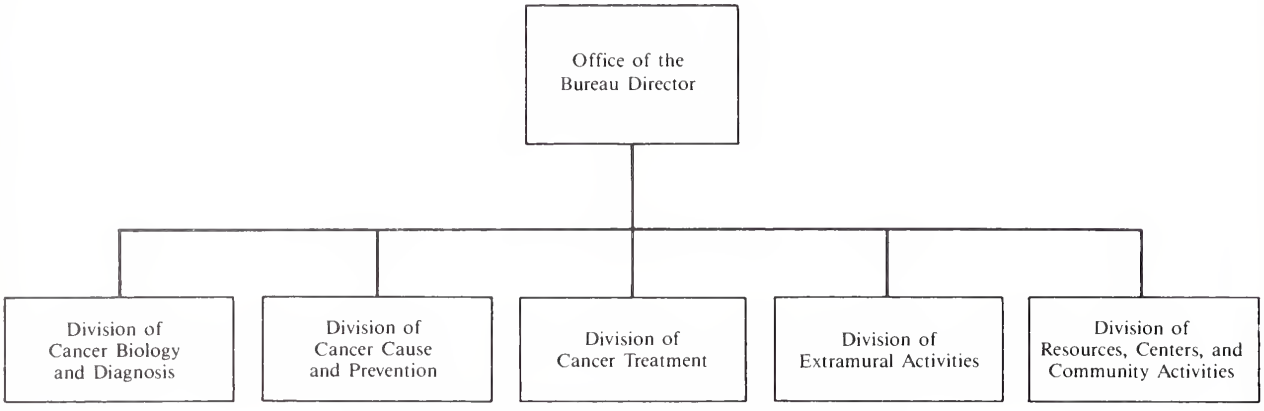

FIGURE 6.2.—Divisions of the National Cancer Institute.

Preface

This handbook is a general guide to assist principal investigators and project directors who are unfamiliar with the contracting process. The questions most frequently asked by the principal investigator once a contract has been awarded are answered. Although emphasis is on the administration of contracts, the initiation and award phases are also addressed.

We hope that this handbook will prove beneficial to the reader. In no way does it replace the Federal Procurement Regulations or the terms of any particular contract.

Appendix B: Guide to the Principal Investigator of NCI Contracts [1]

Research Contracts Branch [2]

BASICS OF CONTRACTS

National Institutes of Health: Role and Mission

General Information About the NIH Contracting Process

The National Institutes of Health (NIH) is the principal health research component of the Department of Health, Education and Welfare [now the Department of Health and Human Services (DHHS)]. Its mission is to conduct and support research on the nature, prevention, detection, diagnosis, and treatment of a disease. In addition to conducting research projects in its facilities, the agency also supports and procures scientific investigations by other organizations under the grants and contracts funding mechanisms.

Definition of a Contract

A contract is an agreement enforceable by law between two or more parties to do a lawful thing according to form for a consideration and within a certain time frame.

Types

Research and Development

Research and development contracts involve a single contract or two or more similarly related or interdependent contracts. These contracts are designed toward the attainment of new or fuller knowledge and understanding of a subject, or the use of such knowledge and understanding, or both, for the development of useful materials, devices, systems, or methods. The terms include, but are not limited to, development and utilization of resources, testing, demonstrations, preparation of reports, and production of experimental or test models necessary or incidental to a research and development activity. However, it excludes quantity production and routine product testing and quality control.

Resource (Support) Projects

Resource or support project contracts include routine screening activities, procurement of equipment, production and procurement of chemical and biological materials, routine pharmacology and toxicology research, purchase of information, conference support, and administrative support activities. Generally, support contracts represent procurement necessary to maintain the research and development effort that is not available within the Government.

Fixed-Price

Most research contracts at the NIH are not of the fixed-price type. However, the most frequently used fixed-price contract is the firm fixed-price type.

Firm Fixed-Price

Description.—This type of contract places maximum risk upon the contractor. It can be adjusted. Therefore, it is the contractor who assumes full responsibility in the form of profits and losses for all costs under or over the firm fixed-price. Thus the contractor has maximum incentive to control costs and meet the required specifications.

Application.—The firm fixed-price contract is appropriate when 1) reasonable definite design or performance specifications are available, and 2) a fair and reasonable price can be established at the beginning.

Cost-Reimbursement

Description.—A cost-reimbursement contract provides for payment to the contractor for allowable and allocable costs incurred in the performance to the extent prescribed by the contract. This type of contract establishes an estimate of total cost for the obligation of funds and a limitation which the contractor may not exceed (except at his risk) without the written approval of the contracting officer.

Application.—This type of contract is suitable for use only when the uncertainties involved in contract performance are of such magnitude that the cost of performance cannot be estimated with sufficient reasonableness.

Types of Cost-Reimbursement Contracts

Cost

Description.—The cost contract is a type of cost reimbursement under which the contractor receives no set fee.

Application.—An illustrative situation in which the use of this type of contract may be appropriate is research and development work, particularly with nonprofit institutions.

Cost Sharing

Description.—A cost-sharing contract is one under which the contractor receives no set fee but is reimbursed for an agreed portion of its allowable costs.

Application.—A cost-sharing contract is suitable for procurements that entail production or research projects which are jointly sponsored by the Government and the contractor. The contractor is prepared to absorb a portion of the costs of performance. Health and Human Services

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[1] Previously published as NIH Publication 80-2239, September 1980.

[2] National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health and Human Services, Bethesda, Maryland 20205.

Procurement Regulations state that cost sharing is required on all unsolicited proposals submitted by institutions having cost sharing agreements with DHHS. The following are illustrative situations in which this type of contract is desirable: jointly sponsored research and development work with nonprofit institutions, and other research and development work the results of which may have commercial benefit to the contractor.

Cost-Plus-Fixed-Fee

Description.—The cost-plus-fixed-fee contract is a cost-reimbursement type which provides for the payment of a fixed fee to the contractor. The fixed fee, once negotiated, does not vary with actual cost but may be adjusted as a result of changes in the work or services to be performed under the contract.

Application.—The cost-plus-fixed-fee is suitable for use when the contract is for the performance of research or preliminary exploration or study, but the level of effort is unknown.

Contracting Process

The research contracting process evolves in the following sequence:

1) Aware of the necessities and opportunities for biomedical research and development, a technical staff member, usually the project officer-designate, develops the concept for a project. This idea is usually developed through his/her initiative, discussions with advisory groups, and interaction with other members of the scientific community. Program officials then ensure that the concept is in accordance with peer review regulations. Institute staff convene and decide whether the project is scientifically relevant and feasible.

2) The project officer and the contract specialist develop a project plan that documents the nature of the required work and its approximate cost, relevance, and priority in the program area.

3) The contract specialist then prepares a Request for Proposal (RFP) based on the information contained in the project plan. The RFP conveys to prospective contractors the information needed to prepare a proposal and provides the basis for evaluation of proposals. The *Commerce Business Daily* and the "NIH Guide for Contracts and Grants" advertise the Government's desire for proposals.

4) Proposals are reviewed by a panel of experts in research and development, 75% of whom are non-Government, for technical merit and acceptability strictly according to previously developed evaluation criteria that appear in the RFP. They are numerically rated by their technical merit and acceptability by a review panel. Proposals considered to be acceptable are ranked in descending order of preference.

5) The negotiating team, consisting of the contract specialist and project officer, begin negotiating with those offerors whose proposals are in the *competitive range* (*see* Glossary).

6) The contract is awarded on the basis of technical merit, cost, and other factors.

7) The contract specialist and project officer monitor the performance of the contract. During the period in which the contract is in effect, the results of the research project may be made available to the scientific community and utilized in future biomedical research and development endeavors.

8) The contract may expire, be renewed, terminated, competed, or recompeted depending on the acceptability of the results, the current need for this project to continue, the availability of funds, or other determining factors.

Important Documents of Information

For the principal investigator to execute his/her duties effectively under the contract, he/she must obtain a copy of the following items from the business office of his/her institution: 1) copy of proposal and its revisions, 2) copy of contract, and 3) the results of any negotiation in writing.

The principal investigator should know that the scope of the work in the proposal which was sent in response to the RFP is not necessarily the same as the one in the contract. Changes may have been made in the work statement. He/she should not only familiarize himself/herself with the general provisions of the contract, but, because his or her name appears on the contract, the principal investigator should also understand its contents and general provisions. Any inquiries about the contents of the contract should be addressed to the contracting officer by the business office of the organization to which the contract was awarded. Any questions about interpretation of the technical aspects of the contract should be directed to the project officer. The principal investigator should review the results of the negotiation so that he/she is entirely familiar with all the contractual obligations.

Differences Between a Grant and Contract

The primary distinction between a grant and contract is that a grant is an agreement to support research and a contract is an instrument used to procure research.

A grant is an award of funds for a specified research activity upon review by a panel of experts of an application by a scientific investigator or institution. The recipient assumes legal and financial responsibility and accountability both for the awarded funds and for the performance of the grant-supported activity. A grant represents a merging of common interests between the grantor and grantee who are both in pursuit of activities considered to be of mutual interest and concern. It entails ideas originated and defined by the grantee. Grant applieations are approved and funded based on consideration of merit and relevance to the program objectives of the grantor organization. Supportive in character with the objective of strengthening an investigator's opportunities for making valuable contributions to the NIH mission, a grant is made to educational and nonprofit institutions to the exclusion of commercial organizations. Extensive freedom is given to the grantee as of this writing.

A contract, on the other hand, offers competitive opportunities to all types of scientific sources and is used by the awarding agency as a means of fulfilling its program objectives. In contrast to a grant, the contract is a procurement device to obtain, for an established cost, a specified performance of an identifiable end with specific terms. A contract, a legally binding agreement involving an offer and

acceptance, is used when the purposes of Government require the services, capabilities, or resources of the non-Federal sector. Because the Government defines the area of work to be undertaken by contract, offerors can compete for a commonly understood requirement. Contract proposals received are evaluated within the framework of technical evaluation criteria announced to all competing sources.

A contract is carefully monitored; a definite project plan must be completed within the time and money constraints of the contract. It is the contractor's responsibility to perform to the best of his/her ability, and if the Government is dissatisfied with his progress, it has the right to terminate the contract.

ROLE OF THE NATIONAL CANCER INSTITUTE PERSONNEL

Site Visits

A site visit is that procedure of evaluation used to assist in the determination of an offeror's capability of performing a new contract or in assessment of progress of an ongoing contract. The project officer has the prerogative to make site visits to the contractor's facility if he desires a firsthand account of how well the contractor is performing. The project officer should inform the principal investigator of the date of his/her arrival as well as the members of the staff who will be coming along. It is to the advantage of the principal investigator to be straightforward in relationships with the project officer.

The Project Officer

The project officer is the Government's representative responsible for the technical monitoring and evaluation of the contractor's performance. It is his/her responsibility to monitor that what the contractor provides the Government is exactly what it has contracted for in quality, timeliness, and economy of price or cost. Constant communication between the principal investigator and the project officer is necessary so that both parties may properly execute their jobs.

The project officer is usually an expert in the field and may be called upon to act as a scientific adviser to the project. It is his/her duty to work with the principal investigator to see that the technical aspects of the contract are performed in the best possible fashion. Although the project officer does not have the authority to direct the principal investigator's staff, interaction between the project officer and co-principal investigator or other professionals on the contractor's staff is not only desirable but necessary for the monitoring of technical aspects of the contract. The project officer should be informed of all progress on the contract and may act as a resource person for the Government. If unfamiliar with a particular area, he/she should seek additional expertise from staff at NIH. It is the project officer's duty to help the principal investigator in any way possible within the scope of the contract.

The project officer *is not* permitted to make any commitments to the contractor regarding such matters as changes in cost, delivery, specifications or other contractual terms. Furthermore, he/she *does not* have the authority to order the start or stop of work. **All changes in the work, services, or delivery schedules must be ordered or approved by the contracting officer before the contractor may proceed with the changes. The project officer does not have the authority to approve purchases or changes in scope of work, travel, modifications, etc. This type of action by the project officer is prohibited by regulations and does not bind the Government to his/her agreement without receiving approval from the contracting officer in writing.**

The Contracting Officer

The contracting officer is the person vested with authority to bind the Government in a contract. This individual has the authority to negotiate, award, and amend contracts on behalf of the Government.

The contracting officer must take action to modify the contract where appropriate by arranging for a justifiable extension of time when this is the only contract change to be made and preparing the suitable documents whenever changes are to be made involving either the scope of work or the funds allotted under the contract, whether or not an extension of time is also involved.

The Contract Specialist

Many of the procedural steps of the negotiation and administration of the contract are performed by the contract specialist, who 1) is subject to the general supervision of the contracting officer and does most of the daily aspects of the contract, 2) is responsible for assuring that the NCI contracting office receives all information about the contractor's efforts, 3) keeps the contractor within the prescribed bounds of activity, and 4) assures compliance with all terms of the contract. To execute his/her duties successfully, the contract specialist relies on help from the project officer and depends on the project officer for interpretation of the contractor's technical progress reports.

Approvals required under the contract must be issued so that work proceeds in an orderly fashion and that the contractor is paid. In conjunction with the project officer, the contract specialist reviews vouchered costs and clears them for payment; approves subcontracts and purchase orders to vendors according to the terms of the contract; authorizes the loan of Government property in keeping with the terms of the contract; and approves the contractor's proposals concerning overtime, special travel, etc.

The contract specialist also follows the contractor's activities to assure compliance with terms of the contract by acquiring and maintaining familiarity with the requirements and objectives of the project, establishing rapport with the project officer and principal investigator, ascertaining that the contractor is submitting the required number of progress reports, and by determining that Government-furnished property is being used for its properly intended purpose.

Action must be taken to close out the contract, which includes: taking appropriate action to verify the necessity and justification for contract termination for the convenience of the Government, assuring that all government property in the contractor's possession is accounted for,

and arranging formal acceptance of the contractor's work, authorizing payment of a final voucher, and taking part in redetermination negotiations when the contract contains such a provision.

METHODS OF REPORTING

Technical Reporting

The contractor is responsible for the timely and satisfactory performance of the contract. Technical reports which are provided by the principal investigator to the contracting officer and the project officer are one of the best ways they can assess the quality and progress of the work being performed. The work statement in the contract outlines the technical work to be accomplished under the terms of the contract, and the technical performance of the contractor is monitored and evaluated against it.

The project officer must receive technical reports to evaluate the contractor's performance. It is the Government's right to request data or information that the contractor produces during the course of the contract; this information should be summarized in the technical progress reports.

Technical reporting by the contractor may take many forms. In almost all instances, a contract will require the submission of interim progress reports plus a comprehensive final report at the completion of the contract. The specific reports required may vary considerably depending on the type of contract, the type of data or other products that will be generated, and the needs of the program area.

The specific technical reporting requirements should be developed jointly by the project officer and the contracting officer. Their consultation with the contractor is often helpful in developing an effective reporting plan. The reporting requirements should be agreed upon at the beginning of the contract and spelled out in the contract in as much detail as possible.

The principal investigator is responsible for developing the progress reports; they may be informal (e.g., letters) or may be as formal as necessary. Reports may include the following: the facilities devoted to the work; the number of staff-days expended for the direction of the work; pertinent experimental details; the kind and number of experiments being conducted; and, in particular, the latest scientific data, observations, and problems encountered with either technical aspects, financial matters, or personnel, predictions, and plans for the next reporting period. The project officer should review the report carefully and approve it if acceptable. In addition to serving the project officer as a principal monitoring tool, progress reports serve as mechanisms for making the results of contract-supported research available to the scientific community. The only exceptions to this are imminent publication of the research results or exemption of the material from the provisions of the Freedom of Information and Privacy Act.

Financial Reporting

Financial reports are necessary for contract administration especially in cost-reimbursement contracts. Financial reports reveal the financial status of the contract and provide helpful information in anticipation of cost overruns or underruns. This type of cost information provides the project officer and the contracting officer with a check on the contractor's expenditure based on cost elements and permits the matching of costs incurred with technical results achieved.

Information obtained from financial status reports provides the principal investigator, project officer, and contracting officer an indication whether the work is progressing (with regard to performance, cost, and time) as called for by the contract. Many contracts include specific procedures for financial reporting in the terms. The principal investigator should request a copy of the reports that are submitted by his/her institution's business office to the NCI contracting office.

It is crucial that the principal investigator be constantly aware of his/her expenditures. He/she should compare them with estimated costs and determine whether the technical performance matches the expenditures and remaining funds. Of the two methods the contractor may use for financial reporting, his/her choice may be determined by the type of system used by the business office of the particular institution. The first method is to receive monthly financial reports as well as a copy of all vouchers being sent to NCI for payment. Thus he/she can review the vouchers, and the financial report can be reviewed for accuracy of all charges. The second method is for the principal investigator to keep his/her records of expenses that can then be compared with the financial report for a final determination of whether they match.

It is important for the business office to submit vouchers and financial reports to the Government on a regular and timely basis. The business office is obligated to submit financial reports or the Government may refuse to pay any additional costs. The Government has the right to perform an audit at any time. An audit is a review or examination of records by a qualified person who determines and reports on whether 1) financial operations are properly conducted, 2) funds are properly allocated, 3) financial reports are presented fairly, and 4) whether there has been compliance with applicable laws, regulations, or contract provisions.

Any problems that involve insufficient funds to complete work, personnel, or other areas which may affect the cost or completion date of the contract should be communicated immediately to the business office. Many times the business office will suggest a procedure that the principal investigator should take in solving the problem. In addition to communicating the problem to the business office, the principal investigator must notify the contracting officer of the problem. Any delays in communicating these problems may affect the status of the principal investigator's performance because delays in committing funds to the project may occur.

Reports Required From the Principal Investigator

The following requirements to which the principal investigator must adhere apply to all contracts. The contract specifies the number of copies of technical reports that must be submitted, their frequency and distribution, and often the content.

Summary of Salient Results

The principal investigator shall submit with the final report a summary (not to exceed 200 words) of the results achieved during the performance of the contract.

Annual/Final Reports

The principal investigator shall submit annual and final reports which summarize the results of his/her work for the period covered. Final reports shall be required before the end of the contract period. Annual reports are required when requested by the project officer (usually 2 months before the end of the 1-year period).

APPROVAL OF COSTS, MODIFICATIONS, AND SUBCONTRACTS

Approval of costs

The principal investigator must obtain prior approval for all costs not specifically included in the contract. Among the most common of these special approvals are travel and purchase of additional equipment.

Travel

Most contracts specify an amount for reimbursement of travel expenditures. Travel by the principal investigator and others can assume several forms: 1) special travel for consultation with another contractor or program official regarding a problem encountered in direct performance of the work or for discussion of progress under the contract, 2) a periodic working conference attended by all contractors participating in a program directed and scheduled by the program director, 3) an essential visit for proper conduct of the project; and 4) attendance of contractor's personnel at scientific meetings.

All categories of travel require specific prior authorization. Scientific meeting travel requires prior written approval of the contracting officer based on the advice and recommendations of the project officer. The potential benefits to NIH must be carefully weighed against the cost of travel and the absence of staff from the laboratory. Even though the meeting may be of interest to the principal investigator and his/her staff, it may be of marginal benefit to the performance of the contract.

Overtime

The contractor must write a letter requesting overtime unless agreed upon as an advance understanding and incorporated in the contract. The letter must include a complete explanation and justification. The contracting officer considers the request and consults the project officer. If they both agree that the request is reasonable, the contracting officer sends a contracting officer authorization letter to the contractor specifying the extent of the Government's commitment in paying the overtime expenses.

Equipment

The contractor should submit a request for the purchase of additional equipment that is not specified in the contract; the request must justify research needs. The contracting officer and project officer review the proposal and decide whether it is technically and financially sound for completing the contract satisfactorily. If they decide that the request is reasonable, the contracting officer issues an authorization for the equipment they deem justifiably necessary for completion of the contract.

Several of the other special approvals will be discussed in their respective sections. These include the following: key personnel, publishing and patent rights, and protection of animal and human subjects.

Modifications

A contract modification is a written alteration of the contract articles, such as period of performance, quantity, or price; whether accomplished in accordance with a contract provision; or by mutual agreement of the parties. Contract modifications must be made in writing by the contracting officer to prevent misunderstanding between the parties concerning the work to be performed. There are two basic kinds of modifications.

Modification Made in Accordance with Contract Clauses

Contract terms and provisions provide for modification to a contract if certain conditions arise or if information not known at the time of contract award becomes available. The standard changes clause present in most contracts states that the contracting officer may unilaterally direct the contractor to make certain changes within the general scope of the work to be followed by equitable adjustments in estimated cost or performance dates as the changes make necessary.

Modification Involving New Procurement Action

Before initiating a modification, the contract officer must determine whether an actual modification within the scope of the existing contract is being made rather than a "new procurement" outside the scope of the contract. The reason for this care is that new procurement must be conducted as a separate procurement action.

The contract officer and project officer work closely together to ascertain that the contractual issues as well as the technical requirements are maintained. *The only person authorized to modify a contract on behalf of the Government is the contracting officer.* If the changes involve either an increase or decrease in contracting cost, then the price is renegotiated between the contractor and the Government.

Subcontracts

A subcontract is an agreement between a party to an original contract and a third party to provide all or a specified part of the work or materials required in the original. A considerable portion of the funds provided to a prime contractor may pass on to subcontractors. The Government is vitally concerned with the capabilities of the subcontract sources that the prime contractor selects. *The contracting officer is the only person with authority to approve subcontracts.* Review and approval of subcontracts shall be consistent with the amount and character of the subcontract work with the overall character and type of the prime con-

tract. Careful and thorough evaluation of subcontracts prior to placement is particularly important when: 1) The prime contractor's purchasing system or performance is not approved; 2) subcontracts are for items for which there is no competition or for which the proposed prices appear unreasonable, and the amounts involved are substantial; 3) close working arrangements or business affiliations that exist between the prime and the subcontractor may preclude the free use of competition or result in higher subcontract prices than would otherwise be obtained; 4) a subcontract is being proposed at a price less favorable than that which has been given by the subcontractor to the Government, all other factors being comparable; or 5) a subcontract is to be placed on a fixed-price incentive, time and material, labor-hour, fixed-price redeterminable, or cost-reimbursement basis.

Although the prime contractor is responsible for selecting qualified subcontractors and management of the subcontract, the Government's right to review and approve these sources gives some assurance that the subcontractors will, in fact, have the necessary capabilities to perform the work required. In certain cases, the contracting officer will inform the contractor that he/she must subcontract with small business. The Government must ensure that small business concerns receive a fair proportion of the Government's business.

The information required to be submitted by the contractor relative to a proposed subcontract includes: 1) a description of the supplies or services to be called for by the contract; 2) identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected, including the degree of competition obtained; 3) the subcontractor's technical and cost proposals and the prime contractor's analysis of it; 4) identification of the type of subcontract to be used and appropriate subcontract clauses; and 5) a draft copy of the subcontract.

The Government's right to review and approve proposed subcontracts in no way relieves the prime contractor of any responsibility for managing the subcontractor. The project officer will be monitoring the prime contractor's management of subcontractor performance. If the subcontracting performance is not adequate, the project officer will alert the contracting officer to take remedial action through the prime contractor.

IMPORTANT CONTRACT CLAUSES

Limitation of Cost Clause

This clause states that it is estimated that the total cost to the Government for performance of this contract, exclusive of any fee, will not exceed the estimated cost set forth in the schedule. The principal investigator agrees to use his/her best efforts to perform the work specified in the schedule and all obligations under this contract within the estimated cost. If at any time the contractor has reason to believe that the costs which he/she expects to incur in the next 60 days (when added to all costs previously incurred) will exceed 75% of the estimated costs set forth in the schedule, the contracting officer shall be notified. Except as required by other provisions of this contract specifically stated to be an exception from this clause, the Government shall not be obligated to reimburse the contractor for costs incurred in excess of the estimated cost specified in the contract schedule.

Key Personnel

The key personnel are employees of the contractor who are engaged with the contract project and who are considered as essential resources during the selection process. The principal investigator must ensure that these people perform under the agreements of the contract. Before transferring any of the specified individuals to other programs, the contractor shall notify the contracting officer reasonably in advance and shall submit justification for the change. The attachment to the contract that specifies the key personnel may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate. *However, no diversion shall be made by the contractor without the written consent of the contracting officer who, of course, consults with the project officer.*

Publication and Printing

Unless otherwise specified, the principal investigator is encouraged to publish the results of his/her work under the contract. He/she should send a copy of each article submitted for publication to the project officer. When the article is published, the principal investigator should furnish the project officer with a copy of the published version. The principal investigator should acknowledge the funding by the DHHS/NIH whenever publicizing the work under this contract with any media. The acknowledgement should read as follows:

> "This project has been funded at least in part with Federal funds from the Department of Health and Human Services under Contract Number _____. The contents of this publication do not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government." (*See* Clause No. 19 of the Appendix.)

Government Property

Government property means all property owned by or leased to the Government or acquired by the Government under the terms of a contract. Government property includes: 1) Government-furnished property, and 2) that part of contractor-acquired property, the title to which is vested in the Government.

Accessibility of Government Surplus Equipment

Any time the contracting officer approves the principal investigator's request for equipment, he/she checks to see the availability of Government surplus equipment. The project officer searches to see if that piece of equipment is available. He/she then works with the property officer to establish clearance for that particular piece of equipment if it is available.

Disposition of Government Property

Whether equipment may be donated to a nonprofit institution is left to the discretion of the contracting officer and property officer; thus the title of the equipment would be transferred to the contractor. If the program does not require the equipment for another project, the equipment is usually donated to the institution. Disposition of Government property with profit-making institutions follows in accordance with a specified procedure in the contract, i.e., it is returned upon completion of the contract.

Protection of Human Subjects

Under the contract, the contractor bears full responsibility that the performance of all work and services involving human subjects be conducted with every regard for the patient's safety. The following requirements are applicable to all contracts involving participation of human subjects in research, development, demonstration, or other activities performed under the contract:

1) A contract involving human subjects may only be initiated if the scope of the work, initially or by amendment, specifically provides for the participation of human subjects. A statement specifically forbidding human subjects is included in the scope of all other contracts providing for research investigations.
2) A contract for research with human subjects will be awarded only to an institution if the institution can and will assume responsibility for safeguarding the rights of human subjects. The principal investigator for the contract, or for each specific project involving research on human subjects, will be approved for patient care responsibilities by the institution, except for social and psychological studies not involving clinical care.
3) An award cannot be made to the institution until a general or special assurance has been accepted by the Office for Protection from Research Risks, Office of the Director, NIH. *Subjects* are those individuals who may be at risk as a consequence of being studied in research, development, demonstration, or other activities supported by NIH; they may be classified as:
   a) Patients are those who are under the care of a physician, dentist, or other health professionals because they have a diagnosed illness, are in the process of being evaluated (worked up) for disease, relatives of patients when it is appropriate to investigate the familial nature of a disease, or are those individuals under surveillance of a physician with regard to certain nutritional, contraceptive, or prophylactic measures, etc.
   b) Volunteers are individuals without known disease who have agreed to participate in research in a clinical setting or to participate in evaluative studies designed to improve the health of the public. A patient may also serve in a role similar to a volunteer when the study is not intended for the direct benefit of the patient and is not directly related to his disease.

Care of Animals

Before undertaking performance of any contract involving the use of laboratory animals, the contractor shall register with the Secretary of Agriculture of the United States. The contractor shall submit assurance in writing to the Office for Protection from Research Risks, Office of the Director, NIH, identifying the procedures by which the contractor will evaluate the care, use, and treatment of laboratory animals.

1) The contractor shall acquire animals used in research and development programs from a dealer licensed by the Secretary of Agriculture.
2) In the care of any live animals used or intended for use in the performance of this contract, the contractor shall adhere to the principles specified in the most recently published *Guide for Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources.

Public Studies and Surveys

Review and approval requirements for studies involving the use of questionnaires, interview guides for personal visits or surveys, and similar methods require project clearance from the NIH Policies and Procedures Office in accordance with the Federal Reports Act, DHHS, and NIH directives.

TERMINATION AND CLOSEOUT

Delinquency Situations

Any problems which may affect the contractor's ability to perform the work should be communicated to the project officer and contracting officer. When the project officer receives a report of unsatisfactory performance, he contacts the principal investigator to determine the nature of the problem. If nothing is done to improve the quality of performance, the project officer may turn the matter over to the contracting officer for legal action. The contracting officer has the option of proceeding with one of the following actions: 1) The contract schedule may be extended, 2) it may be terminated for the convenience of the Government, or 3) the contract may be terminated for default.

Upon completion of the technical and business reviews, the contracting officer may issue a notice of "failure to perform" to the contractor. The notice requires the contractor to inform the contracting officer of the cause(s) of the delinquency, so that proper determination can be made concerning continuation or termination of the contract. During this time, only the contracting officer should have contact with the contractor.

Types of Termination

Termination for Convenience of the Government

The performance of work under a contract may be terminated in whole or in part (from time to time) by the Government when the contracting officer shall determine that such termination is in the best interest of the Government. Termination of work shall be effected by delivery to the contractor of a "Notice of Termination" specifying the extent to which performance of work under the contract is

terminated and the date upon which such termination becomes effective.

Termination for Default

Termination for default is defined as "the exercise of a contractual right of the Government to terminate, in whole or in part, the contractor's right to proceed by reason of his failure, actual or anticipatory, to perform his obligations under the contract."

Federal Procurement Regulation 1-8.707 specifies that a contract may be terminated for default if the contractor fails to 1) make delivery of the supplies or to perform the services within the time specified in the contract, 2) make progress as to endanger performance of the contract in accordance with its terms, or 3) perform any of the other provisions of the contract.

Because cost-reimbursement type contracts require the contractor only to give his/her best efforts to complete the work of the contract, the provisions for default necessarily differ from those in a fixed-price contract. In a cost-reimbursement type contract, the contractor is entitled to his/her reasonable, allocable, and allowable costs. In a fee-bearing contract, if no items have been delivered at the time of default, the contractor receives no fee; if some are delivered, he receives some payment.

When a cost-reimbursement contract is defaulted, the government has the right to all of the work in process under the contract because payment will be made. When a fixed-price contract is defaulted, the Government may require that the contractor deliver any completed portions. Payments for other items may be negotiated between the contractor and the Government. *Any default action which is improper either in its substance or its form will be converted to a termination for convenience.*

Closeout

A completed contract is one which is both physically and administratively complete and in which all aspects of contractual performance have been either accomplished or formally waived. A contract is complete only after all articles and services called for in the contract have been submitted and accepted by the Government.

Closeout of a Government contract is basically a process of gathering together all essential documents reflecting the completion and satisfaction of a wide list of obligations which are created during the course of the contract. A contract is administratively complete when all payments have been made and all administrative actions accomplished.

RENEWALS AND REVISIONS

A contract to be considered for renewal must fall within the project plan of the program area, meet Justification for Noncompetitive Procurement criteria, and have the approval of the project officer and an in-house group for continuation of the project. Then the contracting officer initiates a request to the contractor for a proposal for renewal.

REFERENCE RESOURCES

(*1*) Government Contracts Guide. Washington, D.C.: Commerce Clearing House, Inc., 1972

(*2*) Office of the Secretary: Control of Property in Possession of Contractors. DHEW Publ No. 74-115. Washington, D.C.: U.S. Govt Print Off, 1974

(*3*) Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources: Guide for the Care and Use of Laboratory Animals. DHEW Publ No. (NIH) 78-23 (rev ed). Washington, D.C.: U.S. Govt Print Off, 1978

(*4*) Office of the Secretary, Department of Health and Human Services: The Negotiated Contracting Process: A Guide for Project Officers. Washington, D.C.: U.S. Govt Print Off, 1977

(*5*) A Guide to the NIH Research Contracting Process. DHEW Publ No. (NIH) 74-491. Washington, D.C.: U.S. Govt Print Off, 1973

(*6*) A Guide for Project Officers (internal publication). Bethesda, Md.: Natl Inst Health, June 1978

(*7*) Research Contracts Branch, National Cancer Institute: NCI Research Contract Procedures (the Orange Book). Bethesda, Md.: Natl Cancer Inst, 1977

(*8*) Management Concepts, Inc.: Contract Administration Course, 1977

(*9*) Continuing Education Division, College of Administrative Science, Ohio State University: Program Officials Guide to Contracting. Columbus, Ohio: Ohio State Univ Press, 1973

(*10*) Council on Government Relations, National Association of College and University Business Officers, Washington, D.C.

APPENDIX

The following are some of the clauses that may be present in your contract:

Clause No. 3—LIMITATION OF COST

(a) It is estimated that the total cost to the Government for the performance of this contract, exclusive of any fee, will not exceed the estimated cost set forth in the Schedule, and the Contractor agrees to use his best efforts to perform the work specified in the Schedule and all obligations under this contract within such estimated cost. If, at any time, the Contractor has reason to believe that the costs which he expects to incur in the performance of this contract in the next succeeding 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost then set forth in the Schedule, or if, at any time, the Contractor has reason to believe that the total cost to the Government for the performance of this contract, exclusive of any fee, will be greater or substantially less than the then estimated cost hereof, the Contractor shall notify the Contracting Officer in writing to that effect, giving the revised estimate of such total cost for the performance of this contract.

(b) Except as required by other provisions of this contract specifically citing and stated to be an exception from this clause, the Government shall not be obligated to reimburse the Contractor for costs incurred in excess of the estimated cost set forth in the Schedule, and the Contractor shall not be obligated to continue performance under the contract (including actions under the Termination clause) or otherwise to incur costs in excess of the estimated cost set forth in the Schedule, unless and until the Contracting Officer shall have notified the Contractor in writing that such estimated cost has been increased and shall have specified in such notice a revised estimated cost which shall thereupon constitute the estimated cost of performance of this contract. No notice, communication, or representation in any other form or from any person other than the Contracting Officer shall affect the estimated cost of this contract. In the absence of the specified notice, the Government shall not be obligated to reimburse the Contractor for any costs in excess of the estimated cost set forth in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination. When and to the extent that the estimated cost set forth in the Schedule has been increased, any costs incurred by the Contractor in excess of the estimated cost prior to such increase shall be allowable to the same extent as if such costs had been incurred after the increase; unless the Contracting Officer issues a termination or other notice and directs that the increase is solely for the purpose of covering termination or other specified expenses.

(c) Change order issued pursuant to the Changes clause of this contract shall not be considered an authorization to the Contractor to exceed the estimated cost set forth in the Schedule in the absence of a statement in the change order, or other contract modification, increasing the estimated cost.

(d) In the event that this contract is terminated or the estimated cost not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract based upon the share of costs incurred by each.

Clause No. 9—SUBCONTRACTS

(a) The Contractor shall notify the Contracting Officer reasonably in advance of entering into any subcontract which (1) is cost-reimbursement type, time and materials, or labor-hour, or (2) is fixed-price type and exceeds in dollar amount either $25,000 or 5 percent of the total estimated cost of this contract, or (3) provides for the fabrication, purchase, rental, installation, or other acquisition of special test equipment having a value in excess of $1,000 or of any items of industrial facilities, or (4) has experimental, developmental, or research work as one of its purposes.

(b) In the case of the proposed subcontract which is (1) cost-reimbursement type, time and materials, or labor-hour which would involve an estimated amount in excess of $10,000, including any fee, (2) is proposed to exceed $100,000, or (3) is one of a number of subcontracts under this contract with a single subcontractor for the same or related supplies or services which, in the aggregate are expected to exceed $100,000, the advance notification required by (a), above, shall include:

(1) A description of the supplies or services to be called for by the subcontract;

(2) Identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected, including the degree of competition obtained;

(3) The proposed subcontract price, together with the Contractor's cost or price analysis thereof;

(4) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data when such data and certificate are required by other provisions of this contract to be obtained from the subcontractor;

(5) Identification of the type of subcontract to be used;

(6) A memorandum of negotiation which sets forth the principal elements of the subcontract price negotiations. A copy of this memorandum shall be retained in the Contractor's file for the use of Government reviewing authorities. The memorandum shall be in sufficient detail to reflect the most significant considerations controlling the establishment of initial or revised prices. The memorandum should include an explanation of why cost or pricing data was, or

was not required, and, if it was not required in the case of any price negotiation in excess of $100,000, a statement of the basis for determining that the price resulted from or was based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. If cost or pricing data was submitted and a certificate of cost or pricing data was required, the memorandum shall reflect the extent to which reliance was not placed upon the factual cost or pricing data submitted and the extent to which this data was not used by the Contractor in determining the total price objective and in negotiating the final price. The memorandum shall also reflect the extent to which it was recognized in the negotiation that any cost or pricing data submitted by the subcontractor was not accurate, complete, or current; the action taken by the Contractor and the subcontractor as a result; and the effect, if any, of such defective data on the total price negotiated. Where the total price negotiated differs significantly from the Contractor's total price objective, the memorandum shall explain this difference;

(7) When incentives are used, the memorandum of negotiation shall contain an explanation of the incentive fee/profit plan identifying each critical performance element, management decisions used to quantify each incentive element, reasons for incentives on particular performance characteristics, and a brief summary of trade-off possibilities considered as to cost, performance, and time; and

(8) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract to be obtained from subcontractor.

(c) The Contractor shall obtain the written consent of the Contracting Officer prior to placing any subcontract for which advance notification is required under (a) above. The Contracting Officer may, in his discretion, ratify in writing any such subcontract; such action shall constitute the consent of the Contracting Officer as required by this paragraph (c).

(d) The Contractor agrees that no subcontract placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis.

(e) The Contracting Officer may, in his discretion, specifically approve in writing any of the provisions of a subcontract. However, such approval or the consent of the Contracting Officer obtained as required by this clause shall not be construed to constitute a determination of the allowability of any cost under this contract, unless such approval specifically provides that it constitutes a determination of the allowability of such cost.

(f) The Contractor shall give the Contracting Officer immediate notice in writing of any action or suit filed, and prompt notice of any claim made against the Contractor by any subcontractor or vendor which in the opinion of the Contractor, may result in litigation, related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(g) Notwithstanding (c) above, the Contractor may enter into subcontracts with (i) or (ii) of (a) above, without the consent of the Contracting Officer, if the Contracting Officer has approved in writing the Contractor's procurement system and the subcontract is within the scope of such approval. (This subparagraph (g) however; shall not be applicable to those subcontracts subject to subparagraph (j) below, if any.)

(h) To facilitate small business participation in subcontracting under this contract, the Contractor agrees to provide progress payments on the fixed-price types of subcontracts of those subcontractors which are small business concerns, in conformity with the standards for customary progress payments stated in the Federal Procurement Regulations, Subpart 1-30.5, as in effect on the date of this contract. The Contractor further agrees that the need for such progress payments will not be considered as a handicap or adverse factor in the award of subcontracts.

Clause No. 11—GOVERNMENT PROPERTY

(a) The Government shall deliver to the Contractor, for use in connection with and under the terms of this contract, the property described as Government-furnished property in this contract, together with such related data and information as the Contractor may request and as may reasonably be required for the intended use of such property (hereinafter referred to as "Government-furnished property"). The delivery or performance dates for the supplies or services to be furnished by the Contractor under this contract are based upon the expectation that Government-furnished property suitable for use will be delivered to the Contractor at the times stated in the Schedule of this contract or, if not so stated, in sufficient time to enable the Contractor to meet such delivery or performance dates. In the event that Government-furnished property is not delivered to the Contractor by such time or times, the Contracting Officer shall, upon timely written request made by the Contractor, make a determination of the delay, if any, occasioned the Contractor and shall equitably adjust the estimated cost, or delivery or performance dates, or both, and any other contractual provisions affected by any such delay. In the event that the Government-furnished property is received by the Contractor in a condition not suitable for the intended use, the Contractor shall, upon receipt thereof, notify the Contracting Officer of such fact and, as directed by the Contracting Officer, either (i) return such property, or (ii) effect repairs or modifications. Upon completion of (i) or (ii) above, the Contracting Officer upon timely written request of the Contractor shall equitably adjust the estimated cost, or delivery or performance dates, or both, and any other contractual provision affected by the return, disposition, repair or modification. The foregoing provisions for adjustment are exclusive and the Government shall not be liable for suit for breach of contract by reason of any delay in delivery of Government-furnished property or delivery of such property in a condition not suitable for its intended use.

(b)(1) By notice in writing, the Contracting Officer may (i) decrease the property furnished or to be furnished by the Government under this contract, or (ii) substitute other Government-owned property for property to be furnished by the Government, or to be acquired by the Contractor for the Government, under this contract. The Contractor shall

promptly take such action as the Contracting Officer may direct with respect to the removal, shipping, and disposal of property covered by such notice.

(2) In the event of any decrease in or substitution of property pursuant to subparagraph (1) above, or any withdrawal of authority to use property provided under any other contract or lease, which property the Government had agreed in the Schedule to make available for the performance of this contract, the Contracting Officer, upon the written request of the Contractor (or if the substitution of property causes a decrease in the cost of performance, on his own initiative), shall equitably adjust such contractual provisions as may be affected by the decrease, substitution or withdrawal, in accordance with the procedures provided for in the "Changes" clause of this contract.

(c)(1) Title to all property furnished by the Government shall remain in the Government.

(2) Notwithstanding subparagraph (1) above, title to equipment purchased with funds available for research having an acquisition cost of less than $1,000 shall vest in the Contractor upon acquisition or as soon thereafter as feasible provided that the Contractor shall have obtained approval of the Contracting Officer prior to acquisition of such property.

(3) Title to equipment having an acquisition cost of $1,000 or more, purchased with funds available for the conduct of research, shall vest as set forth in the contract.

(4) If title to equipment is vested pursuant to (2) or (3) above, the Contractor agrees that no charge will be made to the Government for any depreciation, amortization, or use charge with respect to such equipment under any existing or future Government contract or subcontract thereunder.

(5) The Contractor shall furnish the Contracting Officer a list of all equipment acquired under subparagraph (2) above within ten (10) days following the end of the calendar quarter during which such equipment was received.

(6) All Government furnished property, together with all property acquired by the Contractor, title to which vests in the Government under this clause, is hereinafter collectively referred to as "Government property."

(7) Title to Government property shall not be affected by the incorporation or attachment thereof to any property not owned by the Government, nor shall such Government property, or any part thereof, be or become a fixture or lose its identity as personality by reason of affixation to any realty.

(8) Title to all property purchased by the Contractor, for the cost of which the Contractor is to be reimbursed as a direct item of cost under this contract and which under the provisions of this contract is to vest in the Government, shall pass to and vest in the Government upon delivery of such property by the vendor. Title to other property, the cost of which is to be reimbursed to the Contractor under this contract and which under the provisions of this contract is to vest in the Government, shall pass to and vest in the Government upon (i) issuance for use of such property in the performance of this contract, or (ii) commencement of processing or use of such property in the performance of this contract, or (iii) reimbursement of the cost thereof by the Government, whichever first occurs.

(d) The Contractor shall be directly responsible for and accountable for all Government property provided under this contract. The Contractor shall establish and maintain a system to control, protect, preserve, and maintain all Government property. This system shall, upon request by the Contracting Officer, be submitted for review and, if satisfactory, approved in writing by the Contracting Officer. The Contractor shall maintain and make available such records as are required by the approved system and must account for all Government property until relieved of responsibility therefor in accordance with the written instructions of the Contracting Officer. To the extent directed by the Contractor Officer, the Contractor shall identify Government property by marking, tagging, or segregating in such manner as to clearly indicate its ownership by the Government.

(e) The Government property shall, unless otherwise provided herein or approved by the Contracting Officer, be used only for the performance of this contract.

(f) The Contractor shall maintain and administer, in accordance with sound industrial practice, a program for the utilization, maintenance, repair, protection and preservation of Government property so as to assure its full availability and usefulness for the performance of this contract. The Contractor shall take all reasonable steps to comply with all appropriate directions or instructions which the Contracting Officer may prescribe as reasonably necessary for the protection of Government property.

(g) (1) The Contractor shall not be liable for any loss of or damage to the Government property, or for expenses incidental to such loss or damage, except that the Contractor shall be responsible for any such loss or damage (including expenses incidental thereto):

(i) Which results from willful misconduct or lack of good faith on the part of any of the Contractor's directors or officers, or on the part of any of his managers, superintendents, or other equivalent representatives, who has (sic) supervision or direction of all or substantially all of the Contractor's business, or all or substantially all of the Contractor's operations at any one plant, laboratory, or separate location in which this contract is being performed;

(ii) Which results from a failure on the part of the Contractor, due to the willful misconduct or lack of good faith on the part of any of his directors, officers, or other representatives mentioned in (i) above, (A) to maintain and administer, in accordance with sound business practice, the program for utilization, maintenance, repair, protection and preservation of Government property as required by (f) above, or to take all reasonable steps to comply with any appropriate written directions of the Contracting Officer under (f) above, or (B) to establish, maintain and administer, in accordance with (d) above, a system for control of Government property;

(iii) For which the Contractor is otherwise responsible under the express terms of the clause or clauses designated in the schedule;

(iv) Which results from a risk expressly required to be insured under some other provisions of this contract, but only to the extent of the insurance so required to be pro-

cured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or

(v) Which results from a risk which is in fact covered by insurance or for which the Contractor is otherwise reimbursed, but only to the extent of such insurance or reimbursement.

Any failure of the Contractor to act as provided in subparagraph (ii) above, shall be conclusively presumed to be a failure resulting from willful misconduct, or lack of good faith on the part of such directors, officers, or other representatives mentioned in subparagraph (i) above, if the Contractor is notified by the Contracting Officer by registered or certified mail, addressed to one of such directors, officers, or other representatives, of the Government's disapproval, withdrawal of approval, or nonacceptance of the Contractor's program or system. In such event, it shall be presumed that any loss or damage to Government property resulted from such failure. The Contractor shall be liable for such loss or damage unless he can establish by clear and convincing evidence that such loss or damage did not result from his failure to maintain an approved program or system or occurred during such time as an approved program or system for control of Government property was maintained.

If more than one of the above exceptions shall be applicable in any case, the Contractor's liability under any one exception shall not be limited by any other exception.

(2) The Contractor shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provision for a reserve, covering the risk of loss of or damage to the Government property, except to the extent that the Government may have required the Contractor to carry such insurance under any other provision of this contract.

(3) Upon the happening of loss or destruction of or damage to the Government property, the Contractor shall notify the Contracting Officer thereof, and shall communicate with the loss and salvage organization, if any, now or hereafter designated by the Contracting Officer, and with the assistance of the loss and salvage organization so designated (unless the Contracting Officer has designated that no such organization be employed), shall take all reasonable steps to protect the Government property from further damage, separate the damaged and undamaged Government property, put all the Government property in the best possible order, and furnish to the Contracting Officer a statement of:

(i) The lost, destroyed, and damaged Government property;

(ii) The time and origin of the loss, destruction, or damage;

(iii) All known interests in commingled property of which the Government property is a part; and

(iv) The insurance, if any, covering any part of or interest in such commingled property. The Contractor shall make repairs and renovations of the damaged Government property or take such other action as the Contracting Officer directs.

(4) In the event the Contractor is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the Government property, he shall use the proceeds to repair, renovate or replace the Government property involved, or shall credit such proceeds against the cost of the work covered by the contract, or shall otherwise reimburse the Government, as directed by the Contracting Officer. The Contractor shall do nothing to prejudice the Government's right to recover against third parties for any such loss, destruction, or damage, and upon the request of the Contracting Officer, shall, at the Government's expense, furnish to the Government all reasonable assistance and cooperation (including assistance in the prosecution of suit and the execution of instruments of assignment in favor of the Government) in obtaining recovery.

(h) The Government, and any persons designated by it, shall at all reasonable times have access to the premises wherein any of the Government property is located, for the purpose of inspecting the Government property.

(i) Upon completion or expiration of this contract, or at such earlier dates as may be fixed by the Contracting Officer, any Government property which has not been consumed in the performance of this contract, or which has not been disposed of as provided for elsewhere in this clause, or for which the Contractor has not otherwise been relieved of responsibility, shall be disposed of in the same manner, and subject to the same procedures, as is provided in paragraph (g) of the clause of this contract entitled "Termination for the Convenience of the Government" with respect to termination inventory.

The proceeds of any such disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract, or shall otherwise be credited to the cost of the work covered by this contract, or shall be paid in such other manner as the Contracting Officer may direct. Pending final disposition of such property, the Contractor agrees to take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation thereof.

(j) If the Contractor determines any Government property to be in excess of his needs under this contract, such Government property shall be disposed of in the same manner as provided by paragraph (i) above, except that the Government may abandon any Government property in place and thereupon all obligations of the Government regarding such abandoned property shall cease. Unless otherwise provided herein, the Government has no obligation to the Contractor with regard to restoration or rehabilitation of the Contractor's premises, neither in case of abandonment, disposition pursuant to paragraph (i) above, nor otherwise, except for restoration or rehabilitation costs caused by removal of Government property pursuant to paragraph (b) above.

(k) All communications issued pursuant to this clause shall be in writing.

Clause No. 12—CHANGES

(a) The Contracting Officer may at any time, by a written order, and without notice to the sureties, if any, make changes, within the general scope of this contract, in any one or more of the following: (1) Drawings, designs, or specifications, where supplies to be furnished are to be spe-

cially manufactured for the Government in accordance therewith; (2) method of shipment or packaging; and (3) place of delivery.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, the performance of any part of the work under this contract, whether changed or not changed by any such order, or otherwise affects any other provision of this contract, an equitable adjustment shall be made: (1) In the estimated cost or delivery schedule, or both; (2) in the amount of any fixed-fee to be paid to the contractor; and (3) in such other provisions of the contract as may be affected, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within 30 days from the date of receipt by the Contractor of the notification of change: *Provided, however,* That the Contracting Officer, if he decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However except as provided in paragraph (c), below, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(c) Notwithstanding the provisions of paragraphs (a) and (b), above the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance thereof, shall not be increased or deemed to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until such modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the clause of this contract entitled "Limitation of Cost" or "Limitation of Funds."

Clause No. 14—TERMINATION FOR CONVENIENCE OF THE GOVERNMENT

(a) The performance of work under this contract may be terminated, in whole or from time to time in part, by the Government whenever for any reason the Contracting Officer shall determine that such termination is in the best interest of the Government. Termination of work hereunder shall be effected by delivery to the Contractor of a Notice of Termination specifying the extent to which performance of work under the contract is terminated and the date upon which such termination becomes effective.

(b) After receipt of the Notice of Termination the Contractor shall cancel his outstanding commitments hereunder covering the procurement of materials, supplies, equipment, and miscellaneous items. In addition, the Contractor shall exercise all reasonable diligence to accomplish the cancellation or diversion of his outstanding commitments covering personal services and extending beyond the date of such termination to the extent that they relate to the performance of any work terminated by the notice. With respect to such canceled commitments the Contractor agrees to (1) settle all outstanding liabilities and all claims arising out of such cancellation of commitments, with the approval or ratification of the Contracting Officer, to the extent he may require, which approval or ratification shall be final for all purposes of this clause, and (2) assign to the Government, in the manner, at the time, and to the extent directed by the Contracting Officer, all of the right, title and interest of the Contractor under the orders and subcontracts so terminated, in which case the Government shall have the right, in its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts.

(c) The Contractor shall submit his termination claim to the Contracting Officer promptly after receipt of a Notice of Termination, but in no event later than one year from the effective date thereof, unless one or more extensions in writing are granted by the Contracting Officer upon written request of the Contractor within such one-year period or authorized extension thereof. Upon failure of the Contractor to submit his termination claim within the time allowed, the Contracting Officer may, subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall thereupon pay to the Contractor the amount so determined.

(d) Any determination of costs under paragraph (c) shall be governed by the contract cost principles and procedures in Subpart 1-15.3 of the Federal Procurement Regulations (41 CFR 1-15.3) in effect on the date of this contract.

(e) Subject to the provisions of paragraph (c) above, and subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, the Contractor and the Contracting Officer may agree upon the whole or any part of the amount or amounts to be paid to the Contractor by reason of the termination under this clause, which amount or amounts may include any reasonable cancellation charges thereby incurred by the Contractor and pay reasonable loss upon outstanding commitments for personal services which he is unable to cancel: *Provided, however,* That in connection with any outstanding commitments for personal services which the Contractor is unable to cancel, the Contractor shall have exercised reasonable diligence to divert such commitments to his other activities and operations. Any such agreement shall be embodied in an amendment to this contract and the Contractor shall be paid the agreed amount.

(f) The Government may from time to time, under such terms and conditions as it may prescribe, make partial payments against costs incurred by the Contractor in connection with the terminated portion of this contract, whenever, in the opinion of the Contracting Officer, the aggregate of such payments is within the amount to which the Contractor will be entitled hereunder. If the total of such payments is in excess of the amount finally agreed or determined to be due under this clause, such excess shall be payable by the Contractor to the Government upon demand: *Provided,* That if such excess is not so paid upon demand, interest thereon shall be payable by the Contractor to the Government at the rate of 6 percent per annum, beginning 30 days from the date of such demand.

(g) The Contractor agrees to transfer title to the Government and deliver in the manner, at the times, and to the extent, if any, directed by the Contracting Officer, such information and items which, if the contract had been completed, would have been required to be furnished to the Government, including:

(1) Completed or partially completed plans, drawings, and information; and

(2) Materials or equipment produced or in process or acquired in connection with the performance of the work terminated by the notice.

Other than the above, any termination inventory resulting from the termination of the contract may, with the written approval of the Contracting Officer, be sold or acquired by the Contractor under the conditions prescribed by and at a price or prices approved by the Contracting Officer. The proceeds of any such disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract or shall otherwise be credited to the price or cost of work covered by this contract or paid in such other manner as the Contracting Officer may direct. Pending final disposition of property arising from the termination, the Contractor agrees to take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which the Government has or may acquire an interest.

(h) Any disputes as to questions of fact which may arise hereunder shall be subject to the "Disputes" clause of this contract.

Clause No. 15—RIGHTS IN DATA

(a) *Subject data.* As used in this clause, the term "Subject Data" means writings, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, workflow charts, equipment descriptions, data files and data processing or computer programs, and works of any similar nature (whether or not copyrighted or copyrightable) which are specified to be delivered under this contract. The term does not include financial reports, cost analyses, and similar information incidental to contract administration.

(b) *Government rights.* Subject only to the proviso of (c) below, the Government may use, duplicate or disclose in any manner and for any purpose whatsoever, and have or permit others to do so, all Subject Data delivered under this contract.

(c) *License to copyrighted data.* In addition to the Government rights as provided in (b) above, with respect to any subject data which may be copyrighted the Contractor agrees to and does hereby grant to the Government a royalty-free, nonexclusive and irrevocable license throughout the world to use, duplicate or dispose of such data in any manner and for any purpose whatsoever, and to have to permit others to do so: *Provided, however,* That such license shall be only to the extent that the Contractor now has or prior to completion or final settlement of this contract may acquire, the right to grant such license without becoming liable to pay compensation to others solely because of such grant.

(d) *Relation to patents.* Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(e) *Marking and identification.* The Contractor shall mark all Subject Data with the number of this contract and the name and address of the contractor or subcontractor who generated the data. The Contractor shall not affix any restrictive markings upon any Subject Data, and if such markings are affixed the Government shall have the right at any time to modify, remove, obliterate, or ignore any such markings.

(f) *Subcontractor data.* Whenever any subject data is to be obtained from the subcontractor under this contract, the Contractor shall use this same clause in the subcontract, without alteration, and no other clause shall be used to enlarge or diminish the Government's rights in that subcontractor Subject Data.

(g) *Deferred ordering and delivery of data.* The Government shall have the right to order, at any time during the performance of this contract, or within 2 years from either acceptance of all items (other than data) to be delivered under this contract or termination of this contract, whichever is later, any Subject Data and any data not called for in the schedule of this contract but generated in performance of the contract, and the Contractor shall promptly prepare and deliver such data as is ordered. If the principal investigator is no longer associated with the contractor, the contractor shall exercise its (sic) best efforts to prepare and deliver such data as is ordered. The Government's right to use data delivered pursuant to this paragraph (g) shall be the same as the rights in Subject Data as provided in (b) above. The Contractor shall be relieved of the obligation to furnish data pertaining to an item obtained from a subcontractor upon the expiration of 2 years from the date he accepts such items. When data, other than Subject Data, is (sic) delivered pursuant to this paragraph (g), payment shall be made, by equitable adjustment or otherwise, for converting the data into the prescribed form, reproducing it or preparing it for delivery.

Note: If the contract has been awarded by the Office of Education, the above clause shall be deleted and the following substituted therefore:

Clause No. 15—COPYRIGHT AND PUBLICATION

(a) The term "Materials" as used herein means:

(1) "Final material" is material which has been developed to the extent intended under this contract, and (2) "materials," means any copyrightable work resulting from the contract.

(b) It is the policy of the Office of Education that the results of activities supported by it should be utilized in the manner which would best serve the public interest. To that end, except as provided in paragraph (c) the Contractor shall not assert any rights at common law or in equity or establish any claim to statutory copyright in such materials; and all such materials shall be made freely available to the

Government, the education community, and the general public.

(c) Notwithstanding the provisions of paragraph (b) above, upon request of the Contractor or his authorized designee, arrangements for copyright of the material for a limited period of time may be authorized by the Commissioner, through the Contracting Officer, upon showing satisfactorily to the Office of Education that such protection will result in more effective development or dissemination of the materials and would be in the public interest.

(d) With respect to any materials for which the securing of a copyright protection is authorized under paragraph (c), the Contractor hereby grants a royalty-free, nonexclusive and irrevocable license to the Government to publish, reproduce, deliver, perform, use, and dispose of all such materials, and to make any use of it.

(e) To the extent that the Contractor has the right and permission to do so, the Contractor hereby grants to the Government a royalty-free, nonexclusive and irrevocable license to use in any manner, copyrighted material not first produced in the performance of this contract, but which is incorporated in the materials. The contractor shall advise the Contracting Officer of any such copyrighted material known to it not to be covered by such a license.

Clause No. 19—PUBLICATION AND PUBLICITY

(a) Unless otherwise specified in this contract, the Contractor is encouraged to publish and make available through accepted channels the results of its (sic) work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other work is published and furnish a copy of it as finally published.

(b) The Contractor shall acknowledge the support of the Department of Health, Education, and Welfare whenever publicizing the work under this contract in any media. To effectuate the foregoing, the Contractor shall include in any publication resulting from work performed under this contract an acknowledgement substantially as follows:

"This project has been funded at least in part with Federal funds from the Department of Health, Education, and Welfare under contract number _____. The contents of this publication do not necessarily reflect the views or policies of the Department of Health, Education, and Welfare, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

Clause No. 20—PATENT RIGHTS—DEFERRED (SHORT FORM)

(a) *Definitions.* "Subject Invention" means any invention or discovery of the Contractor conceived or first actually reduced to practice in the course of or under this contract, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(b) *Invention disclosures and reports.* (1) The contractor shall furnish the Contracting Officer:

(i) A complete technical disclosure for each Subject Invention, within 6 months after conception or first actual reduction to practice, whichever occurs first in the course of or under the contract, but in any event prior to any on sale, public use, or publication of the invention known to the Contractor. The disclosure shall identify the contract and inventor, and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and to the extent known, the physical, chemical, biological, or electrical characteristics of the invention;

(ii) Interim reports at least every 12 months from the date of the contract listing Subject Inventions for the period and certifying that all Subject Inventions have been disclosed or that there are no such inventions; and

(iii) An acceptable final report within 3 months after completion of the contract work, listing all Subject Inventions or certifying that there were no such inventions.

(2) The Contractor agrees that the Government may duplicate and disclose Subject Invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(c) *Allocation of principal rights.* (1) After a Subject Invention is identified, the Contractor agrees to assign to the Government the entire right, title, and interest therein throughout the world except to the extent that rights are retained by the Contractor under paragraphs (c)(2) and (d) of this clause.

(2) The Contractor or the employee-inventor with authorization of the Contractor may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (b) (1) of this clause, or not later than 3 months thereafter or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by the Contractor. The information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-6. Each determination of greater rights under this contract shall be subject to the provisions of paragraph (c) "Minimum rights acquired by the Government" of the clause in 41 CFR 1-9.107-5(a), and to the reservations and conditions deemed appropriate by the agency.

(d) *Minimum rights to the Contractor.* The Contractor reserves a revocable, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. Revocation shall be in accordance with the procedure of the clause in 41 CFR 1-9.107-5(d)(2) and (3).

(e) *Employee and Subcontractor Agreements.* Unless otherwise authorized in writing by the Contracting Officer, the Contractor shall:

(1) Obtain patent agreements to effectuate the provisions of this clause from all persons who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers.

(2) Insert in each subcontract having experimental, developmental, or research work as one of its purposes provisions making this clause applicable to the Subcontractor and his employees; and

(3) Promptly notify the Contracting Officer of the award of any such subcontract by providing him with a copy of the subcontract and any amendments thereto.

Clause No. 21—KEY PERSONNEL

The personnel specified in an attachment to this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer: *Provided,* That the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The attachment to this contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

Clause No. 26—FEDERAL REPORTS ACT

(a) In the event that it subsequently becomes a contractual requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is to be used for statistical compilations of general public interest, the Federal Reports Act shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single-time) may be used without first obtaining clearance from the Office of Management and Budget (OMB).

(b) The contractor shall obtain the required OMB clearance through the Project Officer before expending any funds or making public contracts for the collection of data. The authority to expend funds and to proceed with the collection of data shall be in writing by the Contracting Officer. The Contractor must plan at least 90 days for OMB clearance.

NCI Manual for Contract Administration

National Cancer Institute
National Institutes of Health
Public Health Service
Department of Health and Human Services

CONTENTS

NCI Manual for Contract Administration [1]

Research Contracts Branch [2,3]

INTRODUCTION

When negotiation has been completed and a contract has been awarded, the administration of it begins. It does not end until final acceptance of the work effort has been accomplished and the contract is closed with final payment to the contractor. During this period, many actions take place: Technical changes are made; property, approvals, and additional funding are requested; progress reports and vouchers are submitted; and possibly a contract termination or a dispute may arise. Federal Procurement Regulation (FPR) Subpart 1-1.18 sets forth the procedures through which the contractors are informed of their responsibilities. We have prepared this manual to assist contracting and project officers in fulfilling their responsibilities in the postaward contract administration; it supplements HEW(PR)3-57, Contract Administration.

Contract administration is conducted by a contracting officer or his representative, the contract specialist, and the project officer. The contract specialist, whose duties concern the work being performed by the contractor, must provide sound advice to the contractor so that the prescribed work may be performed with the assurance of Government cooperation wherever and whenever possible. In research and development contracts, the necessary data for the evaluation of progress and performance, approval of travel funds, processing of the contractor's requests for aid, etc., are couched in highly technical terms. Because such contracts involve topics of a highly specialized biomedical nature, the contract specialist must rely heavily on the program personnel, who are responsible for interpreting the technical material for him. However, it is important that the contract specialist have at least an informed layman's understanding of the objectives and approach of the program personnel.

Administration calls for efficient handling of a demanding routine. Checking and approving invoices and subcontracts and related tasks involve detailed paperwork. The actual evaluation of progress entails the same complicated weighing of evidence, the same juggling of pros and cons that comprises much of the negotiation task, but, generally, negotiation is not as straightforward as administration.

Relationship Between Administration and Project Officer

Contracts are administered entirely within the framework of the negotiated contract. Nevertheless, in research and development procurement with the terms of agreement broadly stated, the contract specialist has substantial opportunity for making judgments.

The contract specialist is the person who receives all information about the contractor's efforts and assures compliance with all terms of the contract. In the discharge of these duties, the contract specialist works closely with the project officer. For example, the contract specialist relies exclusively upon the project officer for interpretation of the contractor's technical progress reports. He/she must receive this interpretation as soon as possible after the report reaches the project officer, so that the contract can be administered in the light of the latest information. If the project officer is slow in reviewing these reports, the contract specialist is at a distinct disadvantage in monitoring or administering the contract's progress.

The contract specialist and the project officer should realize the difficulty of determining, on the basis of reported technical progress, the progress actually made in accomplishing the purpose of the contract. Because of the nature of all research and many development contracts, an estimate of percent completed is little more than a guess, subject to drastic revision on the basis of later information. This is particularly true with a research contract; it is not uncommon for a great part of the completed work to be nullified considerably by a sudden turn of events. Therefore, a high degree of cooperation between the contract specialist and the project officer is essential for adequate performance. A discussion of some of the duties involved in the administrative function may clarify this relationship.

Duties of the Contract Specialist

The functions of the contract specialist fall into three categories. First he/she must follow the contractor's activities to assure compliance with the terms of the contract by 1) acquiring and maintaining familiarity with the requirements and objectives of the overall project, 2) establishing and maintaining rapport with the project officer and con-

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[1] Previously published for administrative use only, September 1980.

[2] National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health and Human Services, Bethesda, Maryland 20205.

[3] In addition to the use of the Department of Health and Human Services and Federal Procurement Regulations, various procurement instructions and memoranda of the National Cancer Institute, and procedures of the Institute's Contract Closeout Section, the preparers of this manual also referred to the following for source material: "The Negotiated Contracting Process—A Guide for Project Officers," "A Guide for Project Officers (NIH)," and the "Program Officials Guide to Contracting" (prepared by the Ohio State University Research Foundation). The members of the Contract Administration Panel were: Daniel J. Longen, Mary B. Armstead, Joseph McHugh, Mary Farrell, and David Sidransky.

tractor, and 3) keeping abreast of the extent and quality of the contractor's progress reports.

Secondly, he/she must make determinations for issuing approval required under the contract, so that work proceeds in an orderly manner and the contractor is paid progress payments while the work goes forward by 1) reviewing the vouchered costs under cost-type contracts and approving them for payment; 2) determining the degree of completion of the work under contracts to approve payments; 3) approving subcontracts according to the terms of the contract or by amendments; 4) authorizing property in keeping with the terms of the contract, or as otherwise needed; 5) approving the contractor's proposals concerning overtime and other premium wage payments, special travel, etc.; and 6) investigating and issuing determination under the "Disputes" clause of the contract.

Thirdly, he/she must take action to close out the contract by 1) considering possible termination for default when the contractor's work is proceeding unsatisfactorily; 2) taking appropriate action to verify the necessity and justification for contract termination for the convenience of the Government; 3) assuring that all property in the contractor's possession is accounted for, including assignment for loss and damage; and 4) arranging formal acceptance of the contractor's work and authorizing payment of a final voucher.

To discharge these duties efficiently, the contract specialist should ascertain that the project officer evaluated the contractor's progress as accurately as possible. For example, to approve monthly vouchers, he/she must know the degree to which the work is completed. To decide whether to terminate the contract he/she must have actual knowledge of its progress. The actual discharge of many of these duties is routine. The mechanics of expenditure approval are not complicated once the decision for approval has been made. It is making the right decision, which in turn, depends on proper judgment of the contractor's progress that really challenges the specialist.

Duties of the Project Officer

Monitoring and control of a contractor's use and management of resources are essential. The project officer performs a key role in overseeing that the Government obtains exactly what it has contracted for in quality of workmanship, timeliness, and cost. The project officer should 1) notify the contracting officer immediately if performance is not proceeding satisfactorily or if problems are anticipated, so that he/she can take the appropriate action to protect the Government's interests; 2) coordinate with the contract specialist on matters affecting the contract that are outside the scope of the contract; 3) make no commitments to the contractor regarding matters that will affect changes in price, delivery, specifications, or other contractual terms nor authorize the initiation or cessation of work *except as specifically provided* in the contract; 4) recommend, in writing, changes in the contract, including justification for the proposed action (if the contractor proposes a change, it should be put in writing and forwarded to the contracting officer); 5) assure that changes in the work (services) or the delivery schedules, or both, are approved by the contracting officer before the contractor proceeds with any changes.

In regard to the delivery or performance schedule, the project officer should inform the contract specialist immediately when a contractor is behind schedule, state the reasons for the slow down, and coordinate with the specialist the corrective action necessary to restore the delivery or performance schedule of the work.

Furthermore, the project officer should furnish the contract specialist with information on the receipt of reports (when payments are based on their receipt), on trip and conference reports, and all correspondence with and from the contractor. Discussion with the contract specialist of the content of communication with the contractor is recommended for prevention of possible misunderstanding or of the creation of a condition that could be the basis for future filing of claims.

He/she also approves or makes recommendations for disapprovals required by the terms of the contract for subcontracts, travel, etc. On behalf of the program for which the contract was initiated, the project officer is responsible for the review of each voucher or invoice submitted by the contractor and makes recommendations for payment of each.

He/she provides whatever assistance may be required pertaining to patent and copyright problems arising under the contract and determines whether any disclosures or patents arose under the contract and if they were reported in accordance with contract requirements.

When visiting the contractor's establishment during the performance of the contract, the project officer attempts to obtain satisfactory answers to the following questions: Is the contract on schedule? What action has been taken by the contractor to restore the time schedule? Is Government property being used as required? (The contracting officer is to be notified if any adverse conditions are noted.) Are any conditions prevalent that might adversely affect the Government's interests? (Such conditions could include changes in personnel, violation of the Equal Employment Opportunity regulations, overextension of facilities, etc.)

MONITORING OF TECHNICAL PERFORMANCE

The procedure for the postaward contract administration is designed to guarantee that the contractor performs in accord with the obligation that has been accepted. Varying degrees of monitoring and control are essential if the contractor's management and use of resources will be such that the Government will receive exactly what it has contracted for in quality of workmanship, timeliness, and economy of price or cost.

The contractor is responsible for timely and satisfactory performance of the contract. However, the Government can neither rely entirely on the contractor to make sure that the work is progressing as scheduled nor risk poor performance. These failures may cause costly delays in the contract or the program of which it is a part. Thus the Government monitors a contractor's performance closely to ensure that the desired research or results (products or services) are completed and delivered on time.

The most important individual involved in technical monitoring is the project officer. He/she is responsible for providing technical assistance to the contractor when needed and interpreting technical matters for the contracting officer. For the most part, the contracts used in the Department of Health and Human Services (DHHS) are either fixed-price or cost-type contracts. In a research project, a primary function of the project officer is his/her recognition of problems in the early stages of development. If problems which develop in a research project are not recognized in time, major revisions may be required in the contract that will affect the amounts of time, money, and effort allotted to the project. Because the work depends on the contractor's creative ability to meet and overcome unforeseen obstacles, technical evaluation by the project officer is most important in his/her determining the status of progress during the postaward phase of a contract.

Compliance With Technical Requirements

Even though this document deals with postaward administration, one must address the preaward actions and their effects on the contract administration. Successful monitoring of technical requirements of the contract can best be achieved if the work statement is written as specifically or definitively as possible. Phased work statements should be encouraged that will allow easier recognition of progress and problem areas, and measurement of work completed. It is essential that the project officer monitor a contractor's progress closely and identify for the contract specialist potential problems that threaten performance, so that remedial measures may be taken at the earliest possible time.

Deviation From Scope of Work

The second area related to technical monitoring is the notification given by the project officer to the contract specialist when the project is not proceeding satisfactorily. Notification must be given to the contract specialist whenever the contractor deviates from the negotiated scope of work or when problems develop that threaten the project. Project officers generally become aware of the deviations and problems through progress reports, telephone conversations, and discussions with investigators at scientific conferences. Such information must be conveyed to the contract specialist if the rights of the Government are to be protected. Any advice given by the project officer to an investigator performing under a contract that will have an effect on price, schedule, or scope of the work must be given only with the understanding that it is subject to approval by the contracting officer.

Change Orders

The contracting officer must be kept informed of communications with the contractor so that possible misunderstandings or situations that could become a basis for future claims against the Government are prevented. Because the primary responsibilities of the project officer are technically oriented, he/she must inform the contract specialist of any communication relative to technical aspects of a contract that may have an impact on costs, e.g., the substitution of personnel assigned to the project under a contract. No one, not even the contracting officer, can direct (nor should request) the contractor to do anything that is not required in the general and special provisions of the written contract. However, contract provisions can be changed by mutual agreement and unilaterally by the Government when the terms of the contract authorize such changes and the contract is modified to reflect the changes made.

POSTAWARD APPROVALS

The consideration of the following requirements or determinations are frequently required in HEW (now DHHS) contracts:

Travel

Domestic travel is usually negotiated before the start of performance and the dollar amounts are placed in the contract. The contractor can then travel within the terms of the contract. If a particular trip is specified in a contract and the need changes, the contractor must request authorization from the contracting officer to substitute another trip. The project officer must verify that the trip being requested is relevant to the work designated in the contract and that the Government will benefit. The contract specialist and project officer must consider the feasibility of the contractor sharing payment because he/she may derive a benefit from the trip. Consideration must be given to who will travel and his/her contribution to the end result of the contract.

If foreign travel is involved, the role of the project officer remains the same, but the contract specialist must secure the appropriate foreign travel clearances before approving the travel.

Overtime

Payment of overtime is specifically prohibited unless it is approved in advance by the contracting officer. It should not be approved unless the work and time involved are absolutely essential to the successful completion of the project. The project officer must verify the technical justification of the overtime, and the contracting officer must authorize the payment. The contract specialist must verify payment for the correct amount of overtime, i.e., that the hours billed were actually worked.

Key Personnel

During negotiations, certain individuals are designated as key personnel and are listed by name in the contract. If it becomes necessary to change or find a replacement for a member of the contractor's staff who was listed in the "Key Personnel" clause of the contract, the project officer must confirm that the substitute has the same expertise and qualifications as the one being replaced.

The contract specialist must ensure that the addition of an individual to the contract (the substitute) will not effect any change in direct labor costs. The contract specialist should consider any possible changes in the direct labor costs before modifying the contract.

Equipment

The authorization for the acquisition of equipment by purchase or by the Government furnishing the item(s) requires the joint efforts of the project officer, contract specialist, and the property administrator. It is the responsibility of the project officer to decide the scientific necessity of equipment requested by the contractor. He/she must also advise the contract specialist of the amount of usage an item of equipment will have. Through all this, the project officer should bear in mind that the NCI is not in the business of buying general laboratory equipment.

The contract specialist, upon receipt of the technical justification by the project officer, must confirm that no alternate funding is available to the contractor. (Please refer to the letter (p 128) presently used by NCI for guidance in justification of contract financing for the purchase of equipment.)

The property administrator should provide guidance to the contract specialist when vested title to equipment is being reviewed. For example, it is impractical for the administrator to retain title rights for an inexpensive item of equipment or one purchased for an educational institution. He/she should take into account shipping costs, potential obsolescence, and purchase price when considering retaining title to equipment.

Consultants

One function of the project officer is to decide the technical need for a particular consultant and also to ensure that the consultant has the proper expertise for the project.

The contract specialist should verify that the consultant, if a Government employee, is not receiving an honorarium. Consideration must be given to the dollar amount of a consultant's fee. The contract specialist should also explore the possibilities that other projects share the cost of travel when consultants visit an institution to advise on several projects.

Subcontracts

Postaward approvals of subcontracts follow the same procedure as those of preawards. The project officer has to decide on the scientific necessity of a particular subcontract as well as on the technical capability of the subcontractor. The contract specialist should work closely with the prime contractor in the selection of the subcontractor. When appropriate, information shall be solicited from the contractor concerning: 1) purchasing and subcontracting practices; 2) principal components to be subcontracted and the contemplated subcontractors, including degree of competition obtained, cost and price analyses or price comparisons accomplished, i.e., accurate, complete, and current cost or pricing data; and subcontract supervision; 3) types of subcontracts; and 4) estimated total extent of subcontracting.

Review and approval of subcontracts shall be consistent with the amount and character of the subcontract work and with the overall character and type of the prime contract. Moreover, Government involvement in the prime contractor's management responsibilities should be exercised only to the extent necessary for compliance with regulatory demands and the greatest practicable return for its expenditure. Information concerning the following criteria, if appropriate, shall be obtained from the contractor and shall be reviewed and affirmatively evaluated as a prerequisite to approval of subcontracting by the contracting officer: 1) the contractor's purchasing system; 2) a copy of the contractor's request for bids or proposals and copies of all bids or proposals reviewed (at least three, unless the absence of competition is justified); 3) justification of source selection; 4) draft of proposed subcontract, including all terms and conditions of the subcontract consistent with terms and conditions of the prime contract, with adequate explanations of any unusual terms and conditions; and 5) evaluation process of cost breakdown equivalent to the prime contractor's estimate, with no cost breakdown of a fixed-price contract except for inadequate competition.

The contract specialist shall initiate the necessary review and evaluation of subcontracts in a timely manner consistent with the policies and procedures set forth herein and in the FPR. When feasible, adequate knowledge of the foregoing elements essential for review and evaluation shall be acquired for use during negotiations as a basis for the contracting officer's approval before an award. The essential requirements culminating in approval of subcontracting are as follows: 1) The contract is accepted, and a budget estimate for subcontracting is established, provided that *a*) all terms and conditions of the subcontract are acceptable; *b*) the price or cost of the subcontract is reasonable; *c*) the fixed fee, if any, does not exceed policy in HHS Procurement Regulation 3-75.104-2; and *d*) the selection of source is justified. 2) The requirements outlined herein must be fully documented in the contract file. 3) The Financial Advisory Services shall have been consulted for comments as needed. 4) Program concurrence to subcontract work with the proposed subcontractor is required. 5) The individual performing the postaudit of costs claimed and the time of such an audit should be indicated.

TECHNICAL PROGRESS REPORTS

A technical progress report is one of the most important means by which the project and contracting officers are kept abreast of a project's advancement. They rely on the contractor to submit periodic technical reports that will assist them to determine if adequate progress is being made and if the relationship between the resources being expended and the progress being achieved is positive. The report acts as a temporary source of information until a formal publication is released that identifies the scientific results of a project. Besides keeping Government personnel aware of the contractor's progress, the technical progress report also gives those involved in the contract a chance to stop periodically and take stock of their efforts and the intent and specifications of the contract. This point is perhaps more relevant to research than to development contracts. The existence of some specifications, or of some prior knowledge in the field, gives development personnel a constant source of data against which to check their work. However, in research, little or no previous data are available. A theoretical course of reasoning may remain internally consistent and yet may veer away from the stated goal

of the project. The necessity of writing a progress report forces the researcher to evaluate his/her work according to the objective standards of the contractual requirement.

The types and numbers of reports required are specified in each contract. In establishing their number and frequency, the negotiator determines the volume of data upon which the project officer and the contract specialist will base their evaluations. However, if for any reason, the contract specialist believes that the contractor should submit fewer or more reports than the contract stipulates, he/she can change the requirement. If necessary, formal progress reports are easily supplemented by informal written or oral communications. These requirements are identified during the preaward phase, but, if proper consideration is not given to reporting requirements, the capability of monitoring progress after the award will be weakened. Project and contracting officers should consider several factors when determining technical reporting requirements.

The logical scheduling of progress reports is important. For example, the contract should not specify routine quarterly reports if the offeror's proposed work plan or the contract work statement is phased differently. The technical approach may be divided into several distinct phases; thus a progress report at the completion of each phase can be expected to contain more meaningful information. The Request for Proposal (RFP) may specify initially the Government's reporting needs; however, it would be illogical for the project officer to insist that the RFP reporting requirements in the contract be perpetuated, if such reporting fails to take into consideration the successful offeror's phased approach.

Technical Risks of the Project

A project involving an area of research that is new or an approach to a research problem untried should be followed closely by the project officer and contracting officer. Many times reviewers of RFP are doubtful about an approach or concept that a principal investigator will use. In these contracts, reporting requirements must be tailored so that progress is highly visible and risks of failure are reduced. Neither time nor funds should be wasted.

Research Area

Program directors sometimes have a responsibility for assessing contributions of several contractors engaged in related research. Their task is to bring these scientific contributions and results into some meaningful whole. Under these conditions, we would not allow the individual contractor to determine what information included in progress reports is appropriate for the Government's needs. Only a Government representative can identify the information needed to facilitate a comparison and compilation of data obtained from several sources.

Length of the Project, Extensions, and Renewals

A contractor's total reporting obligations should be satisfied before the Government's decision to extend a contract. For example, quarterly reports and a final comprehensive one may be required under a 1-year contract. Usually, the comprehensive report is not due until after the expiration date of the basic contract period. However, if a contract extension is contemplated, the requirement for the final report should not be waived nor deferred to the end of the next increment of performance. Instead, the contractor should be instructed to prepare a comprehensive report in conjunction with his extension (renewal) proposal because the contents of such a report could materially assist the Government's assessment of past and projected work and thereby influence the program management staff's ultimate decision whether to fund a new contract extension. Contracts negotiated by the DHHS are often extended several years before a final report is submitted. In the interim, progress reports should satisfy the twofold purpose of the investigator's partial delivery of scientific findings and his/her providing enough information to enable the program officials to monitor performance effectively. The Government's insistence on prescribed progress reporting data is particularly important in incrementally funded contracts because the program staff's ultimate decision whether to allot additional funds to the contract is facilitated. In general, progress reports should provide the following information: 1) achievement of the aims or objectives as reflected in the work statement, 2) positive and negative results of efforts supported by significant data, 3) problems encountered and their resolutions, 4) applicable data and calculations generated in the reporting period, 5) conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project, 6) recommendations based on analytical conclusions, and 7) description of work contemplated in the next applicable reporting period.

The contracting officer has to ascertain that technical reports are received. All Government personnel involved in the procurement process should be aware of the fact that a portion of the contract funds is allotted to the writing of reports. Therefore, in the event a report is delinquent, the contracting officer should consider withholding payment of vouchers submitted for reimbursement or issue a letter of credit. However, a contractor should be given an opportunity to submit the report within a reasonable time before this action is taken. All contracting officers should use a similar system of monitoring.

Upon receipt of the report, the project officer should interpret it for the contracting officer with respect to progress toward the completion of the work.

NONTECHNICAL REPORTS

Of the two types of nontechnical reports, the first consists of financial reports, vouchered invoices, etc. (Procurement Manual Circular HEW 78.1), which indicate the financial status of the contract. The second type includes those reports designed to ensure contractor adherence to the special clauses in the contract, such as Safety and Health, NIH(RC)-30; Small Business Subcontracting, NIH(RC)-33; and Minority Business Enterprise Subcontracting Program, NIH(RC)-37.1.

Financial Reports

These reports reveal the financial status of the contract and provide information that helps the project and contract officers to avoid or anticipate cost overruns and underruns. The cost information provides them with a check on the contractor's expenditures based on cost elements and permits the matching of costs incurred with the technical results achieved.

Vouchers

Cost-reimbursement Contracts

Vouchers submitted under cost-reimbursement contracts must be promptly reviewed by project and contracting officers who determine that the nature of items and amount claimed are in consonance with the contract terms, represent prudent business transactions, and are within any stipulated contractual limitations. The project officer must ensure that payments are commensurate with technical progress under the contract before recommending that the contracting officer approve the voucher for payment.

Fixed-price Contracts

Under a fixed-price contract, payments may be made in a lump sum upon completion and acceptance of all work under the contract, partial payments upon partial delivery and acceptance, and progress payments.

Although a single lump-sum payment upon delivery and acceptance of all end items may be the simplest procedure for making payments, it is often impractical for several reasons. Thus payment under many fixed-price contracts is made by progress payments based on costs incurred, percentage of completion, or the attainment of a specified stage of completion. The project officer is responsible for reviewing these invoices to ascertain that work completed is commensurate with the percentage of completion claimed and that items received are acceptable before recommending that the contracting officer approve the vouchers for payment.

Withholding of Contract Payments

When work is unsatisfactory or delivery unacceptable, it is important that the project and contracting officers coordinate their efforts to identify the problem promptly and take remedial action.

In accordance with the "Withholding of Payments" clause of the contract, the contracting officer may withhold payment under the contract if the contractor fails to submit required reports when due or fails to perform or deliver required work or services, unless such failure arises from causes beyond the control and without the fault or negligence of the contractor, as defined in the "Excusable Delays" clause, NIH(RC)-70.

Safety and Health Report

All contracts which require the use of hazardous materials or operations shall include a safety clause. The "Safety and Health" clause requires the contractor to comply with applicable safety and health regulations, to certify that all applicable requirements have been or will be met during the course of the contract, and report to the contracting officer, in writing, of any actual or suspected occupational diseases, all accidents and incidents resulting in death, permanent or temporary disability, property damage exceeding $100, incident to work performed under the contract. Both the contracting and project officers, if possible, must review this report and advise the safety officer of any noncompliance with the safety and health provisions identified in the contract.

Small/Disadvantaged Business Subcontracting Program Report

In all contracts of $500,000 or more in which subcontracting opportunities exist, the contractor agrees to develop and submit a subcontracting plan and establish and conduct a small/disadvantaged business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under the contract. In accordance with the "Small/Disadvantaged Business Subcontracting Program" clause, the contractor is also required to maintain records which document procedures adopted to comply with the policies set forth in the clause. The information contained in these records is to be summarized quarterly and submitted to the contracting officer and/or Small Business liaison officer for review.

CONTRACT MODIFICATIONS

Any written alteration in the specification, delivery points, rate of delivery, contract period, price, quantity, or other contract provision of an existing contract is defined as a "contract modification" and includes 1) bilateral actions, such as supplemental agreements and amendments, and 2) unilateral actions, such as change orders, notice of termination, and notices of the exercise of an option.

Methods of Modifications

Some modifications require the consent of the contractor, whereas others do not. Modifications may affect the contract price and delivery schedule, and necessary adjustments must reflect the change. Price and delivery may not be affected or affected so slightly that the administrative cost of revising either element would exceed the savings to either party.

Contract modifications are normally accomplished by use of SF30 and are considered as 1) a change order (written), signed by the contracting officer without the consent of the contractor; and 2) a supplemental agreement, which means "any contract modification which is accomplished by the mutual consent of both parties."

Modifications Versus New Procurement

The distinction between new and other than new procurement is important for contract modifications. Normal changes in design, method of shipping or packing, and place of delivery, can all be considered as falling within the scope of the contract and therefore subject to adjustment. Even "variations in quantity" and "extras" can, within limits, be handled by contract changes as other than new procurement. As for contract work modifications, the distinction rests on whether the modification changes the

nature of the supplies or the overall work requirements as defined in the original contract.

Changes Clause

One method for modification of Government contracts is the standard FPR Changes Clause. The clause varies slightly for different types of contracts, but it essentially provides that the Government is permitted to alter work requirements of items made to Government specifications and to change other features of the contract at its discretion. This provides the flexibility required for making essential changes to the job during performance and assures the contracting officer that the results of the contract will be in full accordance with the needs of the Government. Only the contracting officer or his duly authorized representative has authority to issue a change and he must do so in writing. The right to make changes specified in the clause is stipulated at the time the contract is executed. The Government's exercise of its right to issue a change order may entitle the contractor to an equitable adjustment, but agreement of an appropriate equitable adjustment should not serve as a precedent to the effectiveness of the change.

Change Order

Change orders may be issued by the contracting officer without the consent of the contractor, but they must be issued in writing. Although a change order need not be signed by the contractor to be effective, good policy dictates that the contractor be requested to acknowledge receipt of the order.

Supplemental Agreement

A supplemental agreement is bilateral; it is a new agreement between the Government and the contractor.

Duties of the Project Officer

The project officer must recommend in writing any changes in the contract. He must also include justification for the proposed action. In the event the contractor proposes a change, the project officer is to obtain a statement from him to that effect, prepare statements of recommendation and justification, and forward them to the contracting officer. These actions must be done promptly and allow the contracting officer adequate time to exercise his responsibilities. The project officer will also assure that changes in the work or services and delivery schedules are approved by the contracting officer before the contractor is advised to proceed with the change.

Duties of the Contract Specialist

The contract specialist must take action to modify the contract after receipt of all approved documentation from the project officer, i.e., Justification for Noncompetitive Procurement, project plans, contract modifications, etc. The contract specialist has the right to clarify and question the documents received further and alleviate any apparent conflict of interest.

CONTRACT CLOSEOUT

Definition-HHS Procurement Regulation 3-50-501

A completed contract is an agreement, physically and administratively finished, in which all aspects of contractual performance have been accomplished or formally waived. A contract is physically completed when all services called for under the contract have been supplied and all articles, materials, reports, data, exhibits, etc., have been delivered and accepted by the Government. A contract is administratively complete when all administrative actions have been accomplished, all releases executed, and final payment made.

Procedures for Administrative Closure

Six months prior to the expiration of the contract or as soon as the program officials have made the decision, the contract specialist shall forward a letter to the contractor advising that the contract will expire. The letter will notify the contractor that in the near future instructions will be sent for submissions of all deliverables, reports, vouchers, etc.

Thirty days before the date the contract is physically completed, the contract specialist shall forward to the contractor a completion letter containing instructions for submission of vouchers, reports, etc.

The contract specialist will prepare a record card (Form NIH 543 for fixed-type contracts and Form NIH 435-3 for all other contract types) for later recording of information as events occur.

The Contract Specialist shall submit to the project officer a Certification of Closeout, Form NIH-FL-24, for signature.

Upon receipt, the project officer shall review the contract to determine if all services (i.e., tasks, work effort, etc.) have been submitted, and all articles (i.e., contract and items, reports, data exhibits, etc.) have been delivered and accepted.

If all services have been completed as designated in the contract, and all articles were delivered and accepted, the project officer shall sign the FL-24 and return it to the Contract Closeout Operations Unit.

If all contract requirements have not been met, the project officer shall advise the contracting officer as soon as possible so that appropriate action can be taken.

The contract folders can then be shipped to the NCI Contract Closeout Operations Unit.

The closeout administrator will follow-up with appropriate officials to verify that preliminary documentation required for administrative closure of the contract (i.e., royalty, copyright, patent report, Certification for Closeout, property certification) are received.

If determination regarding overrun funding, prior year funding, or property need be made, the contract file will be returned to the contracting officer, who will make a determination and amend the contract where appropriate.

Upon receipt of the final invoice, the closeout administrator will perform desk audits on all contracts less than $100,000. Field audits will be performed on all contracts of $100,000 or more, and a copy of the audit report will be

submitted to Financial Advisory Services Branch. This branch will conduct a review and forward to the Closeout Operations Unit an Advisory Audit Report, NIH 763.2.

The closeout administrator will then obtain from the contractor properly executed copies of the contractor's release, PHS-3576, and Assignment of Refunds, Reports and Credits, NIH-1943.

The Final Certification of Acceptable Costs for Negotiated Contracts, NIH 1154-3, is then signed by the Chief, Research Contracts Branch, and distributed by the closeout administrator.

The contract is now closed and held in Closeout Operations for 2 years, after which it can be shipped to the Washington National Research Center.

APPENDIX

The importance of the role of the contracting officer in business decisions associated with contracts and the need for independence of the contracting officer was attested to in the past in the memoranda of three National Institutes of Health officials; these memoranda are included in this Appendix.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

TO : BID Directors

DATE: June 30, 1978

FROM : Director, NIH

SUBJECT: The Contracting Officer's Independent Role in Business Management Decisions Under Research Contracts

The Secretary has established as a high-priority goal the improvement of contracting practices throughout the Department. Our discussion at the BID Directors' meeting of June 6 identified the areas in need of strengthening at NIH. As you are aware, a comprehensive NIH plan of action has been developed and submitted to the Assistant Secretary for Management and Budget. The action steps included in the plan are designed to continue refinement of our contracting procedures and to leave no doubt about the NIH's commitment to effective utilization of the contract as a means of supporting certain NIH activities.

One major area of concern which has been emphasized by the Secretary and discussed in Departmental reviews of NIH contracting activities is the need for recognition of the authorities and responsibilities assigned to Federal contracting officers. NIH has long fostered the concept of the scientific project officer and the contracting officer operating as a team. We wish to retain this manner of operation. It is important, however, to emphasize the specific authorities assigned to the contracting officer to act in accordance with the procurement regulations and statutes, including the Federal Property and Administrative Services Act of 1949. These authorities cannot be transferred by the contracting officer to his program counterparts or their supervisors in the Institute settings.

In the event of a dispute as to the authority or the technical procurement position of the senior BID contracting officer, the matter shall be referred to the Director, Division of Contracts and Grants, OA. The Associate Director for Administration, NIH, and the Director, NIH, represent the next two stages of appeal should a difference of opinions remain unresolved.

Donald S. Fredrickson, M.D.

MEMORANDUM

RCB-78-8
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

TO : Division Directors
Administrative Officers
Project Officers

DATE: July 10, 1978

FROM : Director, NCI

SUBJECT: Independence of Contracting Officers

As has been stated many times, the successful accomplishment of our contract program depends upon the teamwork of many parties but primarily the Contracting Officer/Contract Specialist and the Project Officer.

As you know, Secretary Califano has stated that the Contracting Officer's position must be strengthened. This coupled with various criticisms that Contracting Officers are, in many cases, being dominated by the Project Officer indicates that the role of the Contracting Officer must be emphasized. It is clear that the Contracting Officer's exercise of independent authority is fundamental to the validity of Government contractual obligations.

The Contracting Officer is charged with the responsibility of satisfying the technical requirements in accordance with existing statutes and procurement regulations. To that end the Contracting Officer must exercise his best judgment leading to a final decision on each procurement after obtaining advice from program personnel among others.

You are requested to apprise your support staff of the need to recognize the independence of the Contracting Officer and to support the exercise of his responsibilities.

Arthur C. Upton, M.D.

cc: Contracting Officers

MEMORANDUM

RCB-78-7

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

TO : NCI Contracting Officers

DATE: July 5, 1978

FROM : Chief, Research Contracts Branch, OD, NCI

SUBJECT: Review of the Quality of Contract Administration

A structured contract administration system is planned for implementation on December 1, 1978. One year after that implementation a procedure will be initiated whereby 25% of all contracts with an annual funding total of $500,000 or more, for which there has been one year's performance, will be reviewed.

The purpose of the review will be to assess the quality of the contract administration for one year, under the aforementioned structured contract administration system. Furthermore, this review should demonstrate the effects of the scheduled seminars and training courses in 1978, upon our administration of contracts.

These reviews will be conducted by the Chief of RCB, or his designee.

The contracts to be reviewed in excess of $500,000 annual funding will be selected on a random basis upon short notice, since it would of course defeat the purpose of a review to permit time for remedying deficiencies beforehand.

The quality of administration will be assessed on a basis that would include monitoring areas such as:

(a) Effective monitoring of technical progress reports from Program.

(b) Effective surveillance of progress and other types of reports due from contractors. If reports were not received, were the payment withholding clauses implemented?

(c) Were site visits made when those progress or technical reports disclosed a problem requiring a visit?

(d) Prompt periodic invoicing of costs by the contractor.

(e) Adequacy of funding remaining in the contract for performance of the work in the later months of the contract year.

(f) If contractor's requests for contracting officer's authorizations were promptly answered.

(g) When a new Indirect Cost Negotiation Report was received did the Contract Administrator then evaluate its effect upon the adequacy of the contract funding?

(h) Was necessary action promptly taken on any interim advice from the NIH Financial Advisory Services Branch (FASB); or upon legal advice received from the DHEW General Counsel's office?

(i) Were in-process reviews made leading to renewal decisions?

When a report of the review has been prepared a copy will be forwarded to the cognizant Section Head. He will be expected to respond to any noted deficiencies and present his plan for remedying.

J.E. Graalman

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

NATIONAL CANCER INSTITUTE

Reference:

This letter is in response to your recent request for NCI funding for various items of equipment to be used in accomplishing research projects under contract NO1-CP-

There are many requirements which must be met before the Government can provide direct funding under contract for any scientific equipment, but let me briefly restate the DHEW policy regarding the furnishing of equipment to be used under contracts.

This policy simply states that all contractors (profit, non-profit or university) shall provide all equipment, facilities, etc. needed to perform the particular research project under contract. The stringent criteria stated below must be met to consider a departure from this policy.

Criteria

(a) The equipment requested must be for a special purpose;

(b) It must be scientifically essential to the performance of the contract;

(c) It must have special application to this contract and no need or use after contract completion;

(d) There is no practical alternative.

(e) It must be used 100% of the contract.

Among the possible alternatives are the following:

(a) Purchase for your account and recover the purchase price by a depreciation charge to the indirect cost pool over the projected useful life of the equipment;

(b) Share the use of equipment being utilized in other departments or other projects;

(c) Subcontracting;

(d) Leasing.

If you will be obliged to abandon all plans to perform the proposed research and development work if the equipment cannot be acquired at Government expense, please answer the following questions for all items requested:

(a) Why is each item of equipment necessary for direct contract performance? What is its functional application?

(b) Why can you not purchase the equipment?

(c) Why can you not lease the equipment or seek a subcontract for the services?

(i) What quotations have been obtained from prospective lessors?

(ii) What sources have been considered as subcontractors for services that require use of the equipment?

(d) Why is the equipment considered "special purpose" and its use limited to performance under this contract?

(e) When and for what period of time is the property to be utilized?

Upon receipt of your response to the items addressed in this letter, your requests for Government-furnished property will be considered further.

Should you have any questions regarding this matter, please call me.

Sincerely yours,

Research Contracts Branch
National Cancer Institute

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

TO : See Below

DATE: July 10, 1978

FROM : Director, NCI

SUBJECT: Notification of Contractors Unsatisfactory Performance

It has recently been brought to our attention that there have been cases of unsatisfactory performance on the part of Contractors which have not received prompt attention.

Please advise your staff that any instance of unsatisfactory performance, noncompliance with contract terms, or other problems with a Contractor should be brought immediately to the attention of the Research Contracts Branch.

Arthur C. Upton, M.D.

Addressees:
Administrative Officers
Division Directors
Project Officers
Contracting Officers

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE

TO : See Below

DATE: July 10, 1978

FROM : Director, NCI

SUBJECT: Semiannual Report Relating to Monitoring Contractors' Technical Progress

As part of the HEW goal to improve the monitoring of contractors' technical progress, a change in the reporting procedure is necessary.

In the future, the Project Officer will submit a semiannual report to his respective supervisor (or to the person designated by the Division Director) to indicate the status of the technical progress achieved under each contract for which he is responsible. A copy of this semi-annual report will be forwarded to the cognizant Contracting Officer for appropriate action and eventual filing in the official contract file.

This semiannual report should stress, in brief detail, appropriate points resembling those outlined in the Summary of Project Officers Responsibilities. That summary appears on pages 23 and 24 of the DHEW booklet: The Negotiated Contracting Process - A Guide for Project Officers (Rev. Oct. 1977).

For new contracts, the first semiannual report will be due six months from the inception date of the contract. For ongoing contracts, including multiyear contracts, the first semiannual report will be due within the next six months on either the anniversary date or six months after the anniversary date calculated from the inception date of the contract or from the last renewal date of the contract.

Arthur C. Upton, M.D.

Addressees:
Division Directors
Administrative Officers
Project Officers
Contracting Officers

Postaward Contract Administration

Tasks	Responsibilities	
	Project officer	Contracting officer
I. Monitoring of technical performance		
A. Ensure contractor performance in accordance with the contract work statement	X	
B. Inform contracting officer of problems or deviations in the contract work statement	X	
C. Take corrective action (if necessary)		X
II. Postaward approvals		
A. Types of approvals		
1. Subcontract		X
2. Travel		X
3. Overtime		X
4. Equipment		X
5. Key personnel changes		X
6. Publishing and patent rights		X
7. Government property		X
B. Purpose and use of approvals	X	X
III. Technical progress reports (monthly, annual, etc.)		
A. Ensure receipt		X
B. Interpret and advise contracting officer of progress	X	
C. Take corrective action (if necessary)		X
IV. Types/use of nontechnical reports		
A. Ensure receipt of vouchers		X
B. Interpret and advise project officer of progress		X
C. Take necessary action		X
V. Types of contract modifications		
A. Recommend changes	X	
B. Review and approve changes		X
C. Amend contract		X
D. Authorize administrative changes		X
VI. Closing contracts		
A. Ensure receipt of closeout documents from contractor, property administrator, project officer, etc.		X
B. Ensure acceptability of deliverables	X	

GLOSSARY

Acquisition is a process of procurement from the ascertainment of the requirement, the subsequent purchase, or contract for supplies or services to administration of the award instrument, the final disposition of the materials, or services required in the closeout of the contract award instrument.

Agreement (supplemental) is a modification of an existing contract by the mutual action of the parties to it.

Business evaluation is a measuring of a business proposal against the business requirements of the procurement data and the rating of the proposal accordingly.

"Commerce Business Daily" is a widely read daily newspaper, published by the Department of Commerce of the U.S. Government, that contains information on procurement invitations, subcontracting leads, contracts awarded, sales and surplus property, and foreign business opportunities.

Competitive range is the extent of acceptable fiscal outlay of a proposal between two extremes and includes those offerors whose proposals present a possibility for the conduct of meaningful discussions leading to a contract award. The determination of competitive range is based on technical assessment and ratings that are judged by review groups.

Concept review is a determination of the scientific/technical merit of the purpose, scope, and objectives of a proposed project. This review applies to all NCI contracts (i.e., research and resource/support) and must be conducted by a panel of non-Government peers. In its review, the panel must take into account, from a scientific standpoint, the goals of the proposed activity, the availability of the technology, and other resources necessary to achieve them.

Contract is a binding legal instrument which reflects the relationship between the Federal Government and another party, such as a local government or private organization, when the purpose of the instrument is to acquire by purchase, lease, or barter, property or service for the direct benefit or use of the Federal Government. Although the Government plays no direct role in the performance of the activity being procured, it has a substantial involvement through monitoring of performance. The NCI may negotiate any of the following types:

Award fee is a cost-plus-fixed-fee contract that contains an incentive to encourage the contractor to perform better than he otherwise might. In addition to a small fixed fee, the contractor has the opportunity to earn more if the Government judges that he has performed especially well.

Completion is a type that describes the scope of work to be done as a clearly defined task or job with a definite goal or target expressed and with a specific end product required. This type is used for the development of a product or when a final report on the research that resulted in the goal or target being attained is required.

Cost-plus-fixed-fee is a cost reimbursable contract with the addition of a fee to be paid the contractor for performing the work. The fee is the contractor's profit and thus applies to commercial contractors. Certain nonprofit institutions are also paid a fee, but it must be reinvested or used for institution business and cannot be distributed as a profit in any form.

Cost reimbursement is a type used when the costs of a project cannot be accurately predicted. It provides for payment to the contractor of all proper costs incurred during performance up to a limit specified in the contract.

Cost sharing contract is one under which the contractor (if a commercial organization) receives no fee and is reimbursed only for an agreed portion of the allowable costs incurred during performance of the contract. The unreimbursed portion of the cost of performance represents the contractor's contribution to what is, in effect, a joint enterprise.

Fixed-price contract is an agreement by the contractor to furnish designated supplies or services at a specified price which is not subject to adjustment because of performance costs. This type of contract is best suited for procurement for which reasonably definite specifications are available and costs can be predicted with reasonable certainty.

Level of effort contract is one under which the contractor is obligated to devote a degree of effort (labor hours) for a stated period. Usually, the minimum and maximum number and type of labor hours that the Government is purchasing are specified in the contract.

Multiyear contract is one that extends for more than 1 year and is incrementally funded.

Research and development contract is one that is primarily for research as opposed to the acquisition of services and materials in support of it. Such research may be fundamental, applied, or developmental. This type of contract is generally one in which the contractor must be innovative in the development of work processes, etc., and for which development of work specifications is generally not possible. However, the NCI requires a desired end product as part of the overall program mission (which may be in the form of a report).

Resource contract provides services or materials in support of a program. Generally, specifications for these contracts are precisely written, and the contractor is required to follow them. The following are examples of this type: routine screening activities, equipment procurement, production and procurement of chemical and biological materials, routine pharmacology and toxicology studies, general Phase I, II, and III clinical trials, conference support, and administrative support activities.

Subcontract is an agreement between a party to an original contract and a third party who is to provide all or a specified part of the work or materials required in the original.

Task order is an agreement, usually a cost reimbursement contract, which permits the NCI to issue an order against an existing contract. The basic or master agreement results from a competitive procurement which identifies the specific requirements to be ordered in the future. Currently, this type of contract is being used in the DCT Phase I and II Clinical Trials and the National Institute of Environmental Health Sciences Bioassay Training Program. The task order contains its specific scope of work and is used by the master contractor to submit a proposal for each one. Selection for award follows the competitive procurement guidelines.

Contract administration is the management of all facets of the process by an agency to assure that the contractor's total performance complies with his contractual commitments and that the obligations of the Government are fulfilled. Management is conducted within the framework of delegated responsibility and authority.

Contract award is the official authorization to implement the contract and to obligate money against it. This authorization becomes effective on the date that the contracting officer signs the contract on behalf of the Government.

Contract fee for research material is that amount the contractor credits to his contract that was paid by researchers for materials purchased from him. Several contracts now in existence allow investigators to purchase research materials from the contractor at a fixed price. Products are specialized biological materials and other therapeutic substances, e.g., research animals, virus materials, cell cultures, tissue samples, etc., that are usually unavailable elsewhere and would not be available except for the Government's interest. This amounts to the Government establishing and funding a commercial enterprise though not for the purpose of earning a profit.

Contract modification is any written alteration in the specifications, delivery point, rate of delivery, contract period, price, quantity, or other contract provision of an existing contract, whether accomplished by unilateral action in accordance with a contract provision or by mutual action of the parties to the contract. It includes bilateral actions, such as change orders, notices of termination, and notices of the exercise of an option.

Contract negotiator is the Government agent assigned to negotiate the contract up to, but not including, the point of signature. The contracting officer who signs the contract may also have acted as the contract negotiator.

Contract renewal is a funded extension of an ongoing contract beyond its initially established expiration date.

Contract specialist is a person who is subject to the general supervision of the contracting officer and who actually performs most of the procedural steps.

Contracting officer, the Government's authorized agent for dealing with the contractor, has authority to negotiate and award contracts on behalf of the Government and to make changes and amendments to the contract.

Contractor is an organization or person entering into a contract with the Government to perform some specific work. The contractor is legally and financially responsible and accountable to the awarding agency for performance of the contract-supported activity.

Department of Health and Human Services procurement regulations are those applicable to all the Department's procurement activities that implement and supplement the Federal procurement regulations. The regulations are prescribed under the authority of the Federal Property and Administrative Services Act of 1949, as amended. They are codified as 41 Code of Federal Regulations, Chapter 3.

Evaluation criteria are those standards against which proposals are appraised. Offerors must be advised of the criteria in the Request for Proposal and the order of their importance and approximate weight.

Federal procurement regulations are directives that apply to NIH and all other civilian Federal executive agencies to the extent specified in the Federal Property and Administrative Services Act of 1949, as amended, or in other laws. These regulations apply to procurements made within and outside the United States.

Grant is an award of funds for a specified research activity after the review of an application from a scientific investigator or an institution. Normally, it affords the investigator maximum freedom and independence to conduct the research.

Incremental funding is the procedure by which funds for a multiple-year contract are allotted as they become available, usually on an annual basis.

Justification for Noncompetitive Procurement is a document required to provide reasonable proof for the awarding of a contract (new or renewal) without competitive procedures.

Key personnel are employees of the contractor who are engaged with the contract project and who are considered as essential resources in the selection process. (The Government should review the qualifications of any substitutes.)

Negotiation refers to the execution of purchases and contracts without formal advertising. Under negotiated contracts, the lowest offeror, with regard to cost, does not necessarily receive the award. Award is made on the basis of a proposal that offers the greatest advantage to the Government, with price and other factors considered. In research and development contracting, technical competence usually is the paramount consideration.

Negotiation memorandum is a complete record of all actions leading to the awarding of a contract, including the history of the procurement; it explains and supports the rationale, judgments, and authorizations for all decisions and actions.

NIH Guide for Grants and Contracts Supplements are issued as needed by NIH to interested subscribers. The supplements include announcements of contract opportunities for the services of educational institutions.

Phasing is the division of the contractual effort into areas or stages of accomplishment, each of which must be completed and approved before the contractor may proceed.

Principal investigator/project director is a qualified individual designated by the contractor and approved by the project officer to direct the project or program being supported by the contract. This individual, who has primary responsibility for guiding or performing (or both) the work as described in the contract work statement, is not the contractor but an employee of the contractor.

Procurement is the attainment of material or services by purchasing, renting, leasing, or other means from sources outside the Government to the best economic advantage of the Government, within legal and administrative requirements.

Project officer, the Government's technical representative responsible for monitoring the contractor's performance and adherence to the scope of work outlined in the contract, provides technical assistance to the contractor as required and supplies technical advice and interpretation to the contracting officer.

Project plan is a document which describes the essentials of a project; it combines the information of both a procurement plan and contract request. In short, it is a type of omnibus, long-term, contract planning and requisition document.

Project plan renewal is a funded extension of an ongoing project plan beyond its initially established expiration date.

Renewal is the supplemental agreement to an existing contract for continuation of work with a contractor (contract modification action). Usually, such extensions are for 6 months or longer.

Request for proposal (RFP) is the government's invitation to prospective offerors to submit a proposal based on the terms and conditions set forth in it.

Research and development contract project is an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed for the acquisition of new or fuller knowledge and understanding of a subject and the use of such knowledge and understanding for development of materials, devices, systems, or methods. The terms include, but are not limited to, development and utilization of resources, testing, demonstrations, preparation of reports, and production of experimental or test models necessary or incidental to a research and development activity. Quantity production, routine product testing, and quality control are excluded.

Resource (support) projects are the routine screening activities, equipment procurement, production and procurement of chemical and biological materials, routine pharmacology and toxicology studies, purchase of information, conference support, and administrative support activities.

Site visit is the procedure of evaluation by the Government's representative who determines an offeror's capability of performing a new contract or his progress on an ongoing contract by on-site observation and presentations by the investigators.

Sources sought refers to attempts by the Government to determine 1) if qualified potential providers are available to perform a specific requirement and 2) the validity of certain noncompetitive procurements.

Summary of negotiations, prepared by the contracting officer or a contract specialist, sets forth all the significant details relating to the negotiated procurement action and reflects the history of the procurement and the rationale for the judgments supporting the contractual agreement.

Technical evaluation is a comparison of a scientific proposal against the requirements contained in the RFP and a rating of the proposal accordingly.

Technical review committee is any committee or group meeting for the purpose of performing preaward or prerenewal evaluations of the scientific merit of research proposals or contracts, or both. Two types of committees are involved in these reviews: 1) A peer committee, composed of 75% or more non-Government personnel, reviews research and development projects or proposals, and 2) technical groups, composed principally or exclusively of Government employees, review proposals.

Unsolicited proposal is a research and development proposal made to the Government without prior solicitation.

Work statement (scope of work) is the document that states the technical objectives and requirements of a contract.

ACRONYMS

ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
BID	Bureau, Institute, and Division
BSC	Board of Scientific Counselors
C06	Cancer Research Facilities Grant
CCNSC	Cancer Chemotherapy National Service Center
CDC	Centers for Disease Control
CREG	Cancer Research Emphasis Grant
DCBD	Division of Cancer Biology and Diagnosis
DCCP[1]	Division of Cancer Cause and Prevention
DCCR	Division of Cancer Control and Rehabilitation
DCG	Division of Contracts and Grants
DCT	Division of Cancer Treatment
DEA	Division of Extramural Activities
DHEW	Department of Health, Education and Welfare
DHHS	Department of Health and Human Services
DRCCA[2]	Division of Resources, Centers and Community Activities
DRG	Division of Research Grants
DRR	Division of Research Resources
EPA	Environmental Protection Agency
F32	Postdoctoral Individual National Research Service Award
F33	National Research Service Award for Senior Fellows
FCRF	Frederick Cancer Research Facility
FDA	Food and Drug Administration
FPR	Federal Procurement Regulation
FY	Fiscal year
GAO	Government Accounting Office
HRA	Health Resources Administration
IG	Inspector General

[1] Early in 1984, the name of this division was changed to Division of Cancer Etiology (DCE).
[2] Early in 1984, the name of this division was changed to Division of Cancer Prevention and Control (DCPC).

JAUP	Justification for Acceptance of Unsolicited Proposal
K04	Research Cancer Development Award
K06	Research Career Award
K07	Academic Award
N01	Contract
NCAB	National Cancer Advisory Board
NCC	Nutrition Coordinating Committee
NCI	National Cancer Institute
NCP	National Cancer Program
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OAM	Office of Administrative Management
OD	Office of the Director
OHRST	Office of Health Research Statistics and Technology
OMB	Office of Management and Budget
OTA	Office of Technology Assessment
P01	Program Project Grant
P20	Exploratory Grant
P30	Cancer Center Support Grant (CORE)
PHS	Public Health Service
R01	Research Project Grant
R09	Scientific Evaluation Grant
R10	Clinical Cooperative Research Grant
R13	Conference Grant
R18	Cancer Control and Rehabilitation Grant
R23	New Investigator Research Grant
R25	Clinical Cancer Education Grant
R26	National Organ Site Program Grant
R & D	Research and Development
RCB	Research Contracts Branch
RFA	Request For Application
RFP	Request For Proposal
SEER	Surveillance, Epidemiology, and End Results (Program)

SRC	Scientific Review Committee(s)
SRG	Scientific Review Group(s)
T15	Continuing Education Training Grant
T32	National Research Service Award: Institutional Award
T35	National Research Service Award for Short-term Research Training
U01	Cooperative Agreement
U10	Clinical Trials Cooperative Agreement
USDA	United States Department of Agriculture
VA	Veterans Administration

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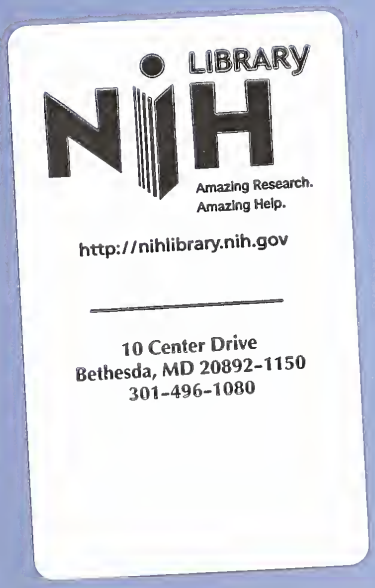
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